Supreme Court, U.S.
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No.

IN THE

Supreme Court of the United States

MEDPOINTE HEALTHCARE INC.,

Petitioner,

v.

HI-TECH PHARMACAL CO., INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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March 17, 2005

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QUESTIONS PRESENTED

1. Whether the Federal Circuit's modification of the preliminary injunction standard to require a patentee seeking a preliminary injunction to demonstrate a "clear case" of patent validity is inconsistent with federal law, which requires a presumption of patent validity, 35 U.S.C. § 282, and inconsistent with the traditional equitable standards governing the grant of preliminary injunctive relief, which require only some likelihood of success on the merits combined with a showing of irreparable harm.

2. Whether the Federal Circuit's application of the "clear case" of patent validity requirement to review only whether a patentee has demonstrated the heightened showing on the merits is improper because it is inconsistent with the traditional purposes of preliminary injunctions to protect the status quo and prevent irreparable harm, as reflected in the balancing analyses applied by this Court and other circuits.

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rule 29.6, petitioner MedPointe Healthcare Inc. states that its parent corporations and publicly held companies that hold 10 percent or more of its stock are MedPointe Inc. and The CPI Development Corporation.

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i

CORPORATE DISCLOSURE STATEMENT ii

TABLE OF AUTHORITIES v

INTRODUCTION 1

OPINIONS BELOW 3

JURISDICTION 3

PERTINENT STATUTORY PROVISIONS 4

STATEMENT OF THE CASE 4

REASONS FOR GRANTING THE WRIT 8

I. THE FEDERAL CIRCUIT ERRED BY RAISING THE BAR ON PATENTEES SEEKING TO OBTAIN A PRELIMINARY INJUNCTION 8

A. The Federal Circuit's Preliminary Injunction Requirement Of A "Clear Case" Supporting Patent Validity Is Contrary to Law 9

B. The Injunction Granted By The District Court Satisfied Traditional Equitable Standards 10

C. The Federal Circuit's Aggressive Application Of The "Clear Case" Of Patent Validity Requirement Was The Basis For Vacating The Preliminary Injunction 12

II. REVIEWING PRELIMINARY INJUNCTIONS SOLELY FOCUSING UPON A HEIGHTENED STANDARD ON THE MERITS IS INCONSISTENT WITH THIS COURT'S PRECEDENT AND THE APPROACHES OF OTHER CIRCUITS 12

TABLE OF CONTENTS (Cont.)

Page

A. The Circuits Apply Conflicting Preliminary Injunction Standards 13

B. The Federal Circuit's Fixation Upon Whether A "Clear Case" Of Validity Has Been Shown Is Improper 16

CONCLUSION 17

TABLE OF AUTHORITIES

Page(s)

Cases

Abbott Labs. v. Mead Johnson & Co.,
971 F.2d 6 (7th Cir. 1992).....14

Al-Fayed v. CIA,
254 F.3d 300 (D.C. Cir. 2001).....15

Amazon.Com, Inc. v. BarnesAndNoble.Com, Inc.,
239 F.3d 1343 (Fed. Cir. 2001).....1, 9, 16

Amoco Prod. Co. v. Village of Gambell,
480 U.S. 531 (1987).....2, 10

California v. Am. Stores Co.,
495 U.S. 271 (1990).....13

Cardinal Chemical Co. v. Morton International Inc.,
508 U.S. 83 (1993).....8, 16

Ciena Corp. v. Jarrard,
203 F.3d 312 (4th Cir. 2000).....14

County Sec. Agency v. Ohio Dep't of Commerce,
296 F.3d 477 (6th Cir. 2002).....15

Déjà Vu of Nashville, Inc. v. Metro. Gov't of Nashville & Davidson County,
274 F.3d 377 (6th Cir. 2001).....14

Dennison Mfg. Co. v. Panduit Corp.,
475 U.S. 809 (1986).....10

Entergy, Ark., Inc. v. Nebraska,
210 F.3d 887 (8th Cir. 2000).....15

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Page(s)

Horton v. City of St. Augustine,
272 F.3d 1318 (11th Cir. 2001).....15

Irwin v. Dixion,
50 U.S. 10 (1850).....13

Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.,
596 F.2d 70 (2d Cir. 1979).....15

Kikumura v. Hurley,
242 F.3d 950 (10th Cir. 2001).....15

Palmer v. Braun,
287 F.3d 1325 (11th Cir. 2002).....15

Polymer Tech., Inc. v. Bridwell,
103 F.3d 970 (Fed. Cir. 1996).....11

Prairie Band of Potawatomi Indians v. Pierce,
253 F.3d 1234 (10th Cir. 2001).....14

Safety-Kleen, Inc. v. Wyche,
274 F.3d 846 (4th Cir. 2001).....15

Sammartano v. First Judicial District Court,
303 F.3d 959 (9th Cir. 2002).....16

Serono Labs., Inc. v. Shalala,
158 F.3d 1313 (D.C. Cir. 1998).....14

United Indus. Corp. v. Clorox Co.,
140 F.3d 1175 (8th Cir. 1998).....14

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Page(s)

University of Texas v. Camenisch,
451 U.S. 390 (1981) 4, 13

Walgreen Co. v. Hood,
275 F.3d 475 (5th Cir. 2001) 15

Weinberger v. Romero-Barcelo,
456 U.S. 305 (1982) 2, 10

Yakus v. United States,
321 U.S. 414 (1944) 13

Statutes & Regulations

28 U.S.C. § 1254(1) 3

35 U.S.C. § 282 ..... 1, 4, 9

35 U.S.C. § 283 ..... 1, 4

Other Authorities

11A Charles Alan Wright, *et al.*,
Federal Practice & Procedure (2d ed. 1995) 13

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23 Loy. L.A. L. Rev. 1215 (1990) 3

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Denlow, Morton, *The Motion for a Preliminary Injunction: - Time for a Uniform Federal Standard*, 22 Rev. Litig. 495 (2003).....3, 13

Landis, James, Note, *Amazon.Com: a Look at Patenting Computer Implemented Business Methods Following State Street*, 2 N.C.J.L. & Tech. 1 (2001) 9

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Leubsdorf, John, *The Standard for Preliminary Injunctions*, 91 Harv. L. Rev. 525 (1978) 3, 13

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INTRODUCTION

This petition arises from a doctrine in the Federal Circuit—the circuit court with exclusive jurisdiction over patent appeals—that imposes a higher standard on patent holders seeking preliminary injunctive relief than on other litigants. For the past several years, the Federal Circuit has imposed upon patent holders seeking a preliminary injunction a threshold requirement that the patentee demonstrate a "clear case supporting the validity of the patent in suit." *See, e.g., Amazon.Com, Inc. v. BarnesAndNoble.Com, Inc.*, 239 F.3d 1343, 1359 (Fed. Cir. 2001). When reviewing preliminary injunctions, if the Federal Circuit decides that a "clear case" has not been demonstrated, that is the end of the inquiry. The preliminary injunction is vacated without considering irreparable harm, balancing the equities, or weighing the value of maintaining the *status quo*.

The Federal Circuit's modification of the preliminary injunction standard in patent cases is inconsistent with federal patent law and inconsistent with the basis for preliminary injunctive relief in the first place, as reflected by this Court's precedent and the preliminary injunction standards of other circuits.

Congress has expressly provided preliminary injunctive relief for patentees, 35 U.S.C. § 283, and mandated a presumption that patents are valid, *id.* § 282. A requirement that patentees must demonstrate a "clear case" of patent validity is essentially a judicially created presumption against the presumption of validity established by Congress. It is also a modification of the traditional standard that a party seeking a preliminary injunction need only show some likelihood of success on the merits along with irreparable injury. A "clear case" on the merits is not required.

Since establishing the "clear case" requirement, the Federal Circuit's practice has been to transform the

deferential review of a preliminary injunction into a *de novo* review of the validity of an issued patent without consideration of other preliminary injunction factors. In the decision below, the district court conducted a three-day evidentiary hearing and issued a 94-page opinion weighing all the factors before granting the preliminary injunction. A divided court of appeals cast aside those findings and entered new findings based on the Federal Circuit's higher standard and a non-deferential review of the merits.

In determining whether to grant a preliminary injunction, courts traditionally consider, in one way or another, (1) whether the plaintiff has an adequate remedy at law, (2) whether the plaintiff will suffer irreparable harm without an injunction, (3) a balancing of the plaintiff's and defendant's harm, (4) whether the plaintiff has a reasonable likelihood of success on the merits, (5) how the injunction will affect the public interest, and (6) the preservation of the *status quo* pending trial on the merits. That balancing analysis follows directly from the fact that "[t]he Court has repeatedly held that the basis for injunctive relief in the federal courts has always been irreparable injury and the inadequacy of legal remedies." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311 (1982); *see also Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 542 (1987). Moreover, a preliminary injunction (and appellate review of a preliminary injunction) is not a procedural substitute for trial (and an appeal) on the merits.

The Federal Circuit's treatment of appellate review of preliminary injunctions conflicts with the purpose of preliminary injunctions and the various balancing analyses used by most circuits. This case is an ideal vehicle to clarify what is and is not proper preliminary injunction procedure, if by nothing else, definitively holding that the Federal Circuit's narrow focus upon the merits, and its requirement of a heightened showing on the merits, are improper. That holding alone would be welcome, as the federal judiciary has

developed a "'dizzying' array of standards" for preliminary injunctions. *See* Hon. Morton Denlow, *The Motion for a Preliminary Injunction: Time for a Uniform Federal Standard*, 22 Rev. Litig. 495, 497 (2003) (quoting John Leubsdorf, *The Standard for Preliminary Injunctions*, 91 Harv. L. Rev. 525, 526 (1978)). Voluminous secondary literature cries out for some clarification from this Court.[1]

OPINIONS BELOW

The Federal Circuit's decision is reported at 115 Fed. Appx. 76 and reprinted in the Appendix ("App.") at 1a-11a. The decision of the United States District Court for the District of New Jersey is reprinted in the Appendix at 13a-89a.

JURISDICTION

The Federal Circuit rendered its decision on November 17, 2004, App. 1a-11a, and denied a timely petition for rehearing on December 17, 2004, App. 12a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

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[1] *See, e.g.*, Lea B. Vaughn, *A Need for Clarity: Toward a New Standard for Preliminary Injunctions*, 68 Or. L. Rev. 839 (1989); *see also* Linz Audain, *On Posner, and Newton, and Twenty-First Century Law: An Economic and Statistical Analysis of the Posner Rule for Granting Preliminary Injunctions*, 23 Loy. L.A. L. Rev. 1215, 1222 (1990) (observing that "the federal courts use two, three, four and five-step standards without any apparent logic to their choice" and that "even their 'four-part' standards differ from each other"); Wolf, Arthur D., *Preliminary Injunctions: The Varying Standards*, 7 W. New Eng. L. Rev. 173, 184 (1984) (disparaging the "widespread disagreement among the courts of appeals regarding the applicable criteria").

PERTINENT STATUTORY PROVISIONS

35 U.S.C. § 282 provides in relevant part:

"A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim."

35 U.S.C. § 283 provides in relevant part:

"The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable."

STATEMENT OF THE CASE

At issue in this case is whether it is consistent with federal law for the Federal Circuit to require patentees seeking a preliminary injunction in patent infringement cases to demonstrate a "clear case" of patent validity, and whether the Federal Circuit errs in limiting its review of preliminary injunctions to the narrow merits issue of whether a "clear case" of patent validity was shown, when the general purposes for granting a preliminary injunction are (1) maintaining the *status quo*, (2) preserving the court's ability to render a meaningful decision, and (3) minimizing the risk of error. *See University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981).

A. General Background

Petitioner MedPointe is a small pharmaceutical company that researches, develops, and markets various branded prescription drugs, including those in the areas of

cough/cold, allergy and respiratory, and pain management. Respondent Hi-Tech is a generic pharmaceutical company that does not develop new drugs but rather sells generic versions of innovator drugs already on the market.

In the spring of 2000, Alexander D'Addio, currently MedPointe's Vice President of Product and Process Development, conceived of a new cough/cold product containing the drugs carbetapentane tannate, phenylephrine tannate and pyrilamine tannate. App. 18a. Carbetapentane tannate is an antitussive (anti-cough), pyrilamine tannate is an antihistamine, and phenylephrine tannate is a decongestant.

The tannate salts of these active ingredients were known to be difficult to work with, and nobody had previously combined these three ingredients in a single product. In Dr. D'Addio's nineteen years of pharmaceutical experience, he deemed these products the hardest to formulate because of their high tannate levels. App. 65a-66a. MedPointe invested approximately $3 million into researching and developing this drug combination. App. 88a.

On January 26, 2001, Dr. D'Addio applied for a patent on the drug combination. The United States Patent and Trademark Office (PTO) examined the application and on July 9, 2002, issued U.S. Patent No. 6,417,206 ("the '206 patent"), which guarantees MedPointe the exclusive right to sell the drug combination.

In Fall 2002, MedPointe launched two commercial products covered by the '206 patent: Tussi-12D tablets and Tussi-12D S suspension. Through October 2003, the combined sales of Tussi-12D products were approximately $15.5 million, with over $11 million attributable to Tussi-12D S. App. 72a. Those products anchor MedPointe's cough/cold business, accounting for approximately 50% of its cough/cold business and much of its total business. In

short, MedPointe's ability to stay in the cough/cold business depends on the performance of its Tussi-12D products.

In Spring 2003, respondent Hi-Tech learned of MedPointe's patented Tussi-12D products, and began developing a copy. App. 21a. Hi-Tech spent only $5,000 to test its copied product, and has conceded that its product would infringe MedPointe's patent if that patent is valid. App. 76a. On the eve of the 2003-2004 cough/cold season, Hi-Tech began offering to sell its copied product, representing it as a substitute for MedPointe's Tussi-12D products by linking it to MedPointe's patented products in nationwide pharmacy databases that identify generic versions of branded drugs.

B. MedPointe's Irreparable Harm.

Hi-Tech's linkage had potentially devastating effects on MedPointe because state laws and insurance plans often require pharmacists to substitute listed generic products for branded products. App. 19a. Once a drug becomes "genericized" in this way, the market cannot revert to its former condition. As is generally true for brand-name drug companies, each time generic substitutes enter the market, MedPointe's sales have plummeted, effectively destroying the markets MedPointe created. For example, when Hi-Tech genericized MedPointe's Tussi-12 reformulated suspension product, MedPointe's sales dropped by eighty percent. They have never recovered.

Those losses affect a significant portion of the company's revenues, and have the potential to result in significant job losses. MedPointe also stands to lose research and development funding for its future products.

C. The District Court Proceedings.

When MedPointe learned that Hi-Tech had linked its copied product to MedPointe's Tussi-12D S in the pharmacy databases, it immediately filed suit seeking a temporary restraining order and a preliminary injunction. App. 84a.

On December 1, 2003, the district court issued a temporary restraining order. The district court conducted a three-day evidentiary hearing on December 22-24, 2003.

Hi-Tech did not contest its infringement of MedPointe's patent at the preliminary injunction hearing. Instead, Hi-Tech argued that MedPointe's patent was invalid as obvious because several other tannate cough/cold products existed before MedPointe's patent was filed, most of which had already been examined by the Patent and Trademark Office.

In the district court, several witnesses testified that the active ingredients used in the previous cough/cold products were of different classes and had both different characteristics and properties than those claimed by MedPointe's patent. Several witnesses further testified about the difficulty of working with tannate salts and that it would ***not*** have been obvious for others to come up with the new patented drug combination in light of the old cough/cold products. App. 65a-66a.

On March 1, 2004, the district court issued a 94-page memorandum opinion, stating its findings of fact, and preliminarily enjoining Hi-Tech pending a trial on the merits. App. 13a-89a. The district court concluded, *inter alia*, that MedPointe had made a "strong showing" of likelihood of success on the merits, and that Hi-Tech had raised no substantial question of invalidity. The district court also recognized that because of MedPointe's large investment in developing Tussi-12D, the company's "continued viability is at stake," and therefore the balance of hardships weighs in MedPointe's favor. App. 87a-88a.

D. The Federal Circuit Proceedings.

On November 17, 2004, a divided panel of the Federal Circuit vacated the preliminary injunction. App. 1a-11a. The majority's decision was based solely on its determination that MedPointe had failed to present a "clear case" that its patent was valid. App. 8a-9a. Chief Judge

Mayer dissented. As an initial matter, Chief Judge Mayer believed that the majority was wrong with respect to this particular case. Pointing to the district court's lengthy consideration of the factual issues, Judge Mayer disagreed with what were essentially three key appellate findings of fact made by the majority: (1) that ammonium chloride was not an active ingredient in the Candettes reference, (2) that tannates are not difficult to work with, and (3) that the commercial success of MedPointe's Tussi-12D product was tenuous. App. 9a-11a.

More significantly, however, Chief Judge Mayer criticized the majority's entire approach toward preliminary injunction review. A preliminary injunction is "to maintain the *status quo* pending a resolution" of the case. App. 9a (Mayer, C.J., dissenting). Judge Mayer described the majority's approach as "*de novo* review of the district court's finding of fact." App. 9a-11a (Mayer, C.J., dissenting). Such a "foray into the virtually exclusive province of the district court has been regularly and consistently criticized by both the Supreme Court and this court." App. 10a.

Panel rehearing was denied on December 17, 2004, along with petitioner's motion to stay issuance of the mandate pending the filing of this petition. App. 12a.

REASONS FOR GRANTING THE WRIT

I. THE FEDERAL CIRCUIT ERRED BY RAISING THE BAR ON PATENTEES SEEKING TO OBTAIN A PRELIMINARY INJUNCTION.

As this Court recognized in *Cardinal Chemical Co. v. Morton International Inc.*, 508 U.S. 83, 89 (1993), the Federal Circuit's "exclusive jurisdiction over appeals from all United States District Courts in patent litigation" makes the rules it applies in patent cases "a matter of special importance to the entire nation." Here, as in *Cardinal Chemical*, the Federal Circuit has adopted a novel rule that

undercuts the value of patents and is inconsistent with the rights granted and the presumptions accorded under the Patent Act. This Court's review is therefore warranted.

A. The Federal Circuit's Preliminary Injunction Requirement Of A "Clear Case" Supporting Patent Validity Is Contrary to Law.

The Federal Circuit in *Amazon.com* decided that a patentee seeking a preliminary injunction must demonstrate, not merely some likelihood of success, but "a clear case supporting the validity of the patent in suit." 239 F.3d at 1359. As the Court of Appeals described its doctrinal modification, "[s]uch a case might be supported, for example, by showing that the patent in suit had successfully withstood previous validity challenges in other proceedings," or that there had been "a long period of industry acquiescence in the patent's validity." *Id.*

A patentee with a new patent, like MedPointe, obviously cannot satisfy that standard by pointing to past litigation or a "long period" of industry practice. The Federal Circuit's review of patent invalidity allows defendants to defeat any preliminary injunction simply by showing that the patent is "vulnerable" to an attack on validity. *See* James Landis, Note, *Amazon.Com: a Look at Patenting Computer Implemented Business Methods Following State Street*, 2 N.C.J.L. & Tech. 1, 15 (2001) ("Very quickly the [Federal Circuit's preliminary] injunction test transforms from balancing to threshold, disregards the presumption of irreparable harm, and shifts and increases the burden of proof to the holder of an officially obtained patent.").

The Federal Circuit's preliminary injunction analysis effectively reverses the burden of proving patent invalidity. Patents are subject to scrutiny before the PTO and are therefore entitled to a presumption of validity. 35 U.S.C. § 282. Consequently, it is the defendant—not the patent holder—who must prove the patent invalid by clear and

convincing evidence. *See Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 810 (1986) (per curiam). The Federal Circuit's preliminary injunction requirement of a "clear case" of patent validity significantly, and unfairly, discounts the presumptive validity of the patentee's right to exclude, particularly where, as here, there is no dispute that the patent is infringed.

The Federal Circuit's approach also deviates from traditional requirements for a preliminary injunction. "The Court has repeatedly held that the basis for injunctive relief in the federal courts has always been irreparable injury and the inadequacy of legal remedies." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982); *see also Amoco*, 480 U.S. at 542. Some likelihood of success on the merits is also required. *See Doran v. Salem Inn, Inc.*, 422 U.S. 922, 931 (1975) ("The traditional standard for granting a preliminary injunction requires the plaintiff to show that in the absence of its issuance he will suffer irreparable injury and also that he is likely to prevail on the merits."). By requiring a patentee to demonstrate a "clear case" of patent validity, however, the Federal Circuit is imposing a non-traditional, heightened showing on the merits, on an issue for which the patentee does not have the burden of proof. Such a new requirement is improper because Congress has not, by a "clear and valid legislative demand," cast aside the "the great principles of equity." *See Weinberger*, 456 U.S. at 313 (quotations omitted). Indeed, Congress expressly directed that injunctive relief in this context adhere to "the principles of equity." 35 U.S.C. § 283.

B. The Injunction Granted By The District Court Satisfied Traditional Equitable Standards.

In this case, the District Court, after a three-day hearing, not only found the patent likely to be valid, but also found that all the other equitable factors supported the issuance of the preliminary injunction. Petitioner presented significant

evidence of irreparable harm without the injunction, including significant and irretrievable loss of market share, job losses, and loss of research and development funding. This evidence was unrebutted, and the district court made findings of fact as to petitioner's significant irreparable harm. App. 81a-89a.

For example, the District Court found "especially credible" the fact that MedPointe would face financial ruin if Tussi-12D is "genericized." App. 87a. As the district court found, "[w]ere genericization to take place, MedPointe's continued viability would be questionable." App. 87a. At a minimum, the district court found that "MedPointe's goodwill would suffer, as would its ability to support and market Tussi-12D by educating physicians in its use." App. 87a. The evidence established that the harm to MedPointe was incalculable, because, as the Federal Circuit has recognized in other cases, a court cannot easily restore a patent holder to the place it held in the market prior to the infringing sales. *See Polymer Tech., Inc. v. Bridwell*, 103 F.3d 970, 976 (Fed. Cir. 1996). An order simply removing the infringing products from the marketplace may not be effective because customers may have established relationships with infringers or turned towards other products. *See id.* All of this evidence of irreparable harm was presented separate and apart from the presumption of irreparable harm that automatically attaches in patent cases.

The Federal Circuit also failed to balance the relative harms and consider the preservation of the *status quo* in this case. The preliminary injunctive relief in this case sought solely to maintain the *status quo*—where the respondent had not yet entered the market and had not yet irreparably harmed MedPointe's market share and goodwill. Chief Judge Mayer aptly noted in his dissent that he would affirm the preliminary injunction "to maintain the *status quo*" pending resolution of the case. App. 9a (Mayer, C.J., dissenting).

C. The Federal Circuit's Aggressive Application Of The "Clear Case" Of Patent Validity Requirement Was The Basis For Vacating The Preliminary Injunction.

The Federal Circuit's heightened standard was outcome-dispositive to this case. The Federal Circuit vacated the preliminary injunction here because it found that MedPointe's patent was "'vulnerable' to attack based on validity," App. 4a, even while conceding that the decision "in no way resolves the ultimate question of invalidity," App. 8a n.5. In fact, as Chief Judge Mayer recognized in dissent, the majority's conclusion about "vulnerability" was based primarily on its disagreement with the district court's factual finding based on the testimony of one witness. App. 9a-11a (Mayer, C.J., dissenting). "The district court, which has special expertise in making credibility determinations, was entitled to disregard [the witness's] testimony, especially in light of [a particular] reference" listed in the patent application." App. 9a-10a. Given that the panel's opinion turned on a narrow disagreement over the evidence before the district court, it is exceedingly likely that had the Federal Circuit applied the appropriate standard, it would have affirmed the issuance of the preliminary injunction.

This case therefore provides a perfect vehicle through which this Court may correct the Federal Circuit's improperly heightened standard for a preliminary injunction in patent cases.

II. REVIEWING PRELIMINARY INJUNCTIONS SOLELY FOCUSING UPON A HEIGHTENED STANDARD ON THE MERITS IS INCONSISTENT WITH THIS COURT'S PRECEDENT AND THE APPROACHES OF OTHER CIRCUITS.

Since its earliest days, the purpose of the preliminary injunction has been to prevent irreparable injury and "to preserve the relative positions of the parties until a trial on

the merits can be held." *See University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981); *see also Yakus v. United States*, 321 U.S. 414, 440 (1944); *Irwin v. Dixion*, 50 U.S. 10, 29 (1850). This Court's precedent requires weighing the full panoply of traditional equitable considerations in deciding whether to grant injunctive relief. *See, e.g., California v. Am. Stores Co.*, 495 U.S. 271, 281 (1990). The Federal Circuit, however, utilizes its requirement of a "clear case" supporting the validity of the patent to review only the merits issue of validity, dispensing with issues of irreparable injury or relative harm. By cutting the traditional equitable inquiry short, the Federal Circuit unduly restricts the availability of the preliminary injunction from the rightful equitable remedies available to plaintiffs in patent cases.

Under traditional standards, the degree of likelihood of success "must be considered and balanced with the comparative injuries of the parties," often described as a "sliding scale" between the factors. *See* 11A Charles Alan Wright, *et al.*, Federal Practice & Procedure § 2948.3, at 189-195 (2d ed. 1995). The Federal Circuit's practice conflicts with the balancing analyses deployed by other circuits. This Court has yet to articulate a detailed standard for granting a preliminary injunction or for appellate review, and considerable divergence has developed in the circuits.

A. The Circuits Apply Conflicting Preliminary Injunction Standards.

Judges and academics have long recognized a circuit split on the standards for determining issuance of a preliminary injunction. *See, e.g.*, Hon. Morton Denlow, *The Motion for a Preliminary Injunction: Time for a Uniform Federal Standard*, 22 Rev. Litig. 495, 497 (2003) (citing John Leubsdorf, *The Standard for Preliminary Injunctions*, 91 Harv. L. Rev. 525, 526 (1978)); Thomas R. Lee,

Preliminary Injunctions and the Status Quo, 58 Wash. & Lee L. Rev. 109 (2001).

The various courts of appeals have developed an assortment of standards in granting a preliminary injunction. Most circuits apply some version of the traditional inquiry and weigh the following factors: (1) whether the plaintiff has an adequate remedy at law, (2) whether the plaintiff will suffer irreparable harm without an injunction, (3) a balancing of the plaintiff's and defendant's harm, (4) whether the plaintiff has a reasonable likelihood of success on the merits, (5) how the injunction will affect the public interest, and (6) the preservation of the *status quo* pending trial on the merits.

For example, the Eighth Circuit considers and balances each factor, but does not require any factor as a threshold. *E.g. United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1178-79 (8th Cir. 1998) (asserting that no single factor is determinative); *see also Ciena Corp. v. Jarrard*, 203 F.3d 312, 322 (4th Cir. 2000); *Déjà Vu of Nashville, Inc. v. Metro. Gov't of Nashville & Davidson County*, 274 F.3d 377, 400 (6th Cir. 2001). Similarly, the D.C. Circuit and the Seventh Circuit balance the factors using a "sliding scale" where "strong" arguments for one factor may support issuance of an injunction despite "weak" arguments in other areas. *E.g.*, *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1318 (D.C. Cir. 1998); *Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 12 (7th Cir. 1992).

Some circuits do not require the movant to establish a "likelihood of success on the merits," but instead allow a preliminary injunction to issue if a plaintiff shows that there are "questions going to the merits ... so serious, substantial, difficult, and doubtful as to make the issue ripe for litigation and deserving of more deliberate investigation." *E.g. Prairie Band of Potawatomi Indians v. Pierce*, 253 F.3d 1234, 1246-47 (10th Cir. 2001) (internal quotation and citation omitted).

Other circuits have instituted different burdens and threshold requirements that must be met before other equitable factors are considered. For example, the Eleventh Circuit requires the movant to establish a "burden of persuasion" as to each of the factors. *E.g. Horton v. City of St. Augustine*, 272 F.3d 1318, 1326 (11th Cir. 2001). The Fifth Circuit requires a threshold showing of "likelihood of success on the merits" before considering other factors. *E.g. Walgreen Co. v. Hood*, 275 F.3d 475, 477-78 (5th Cir. 2001).

Different circuits also consider the various equitable factors in different manners. For example, as to irreparable harm, the Fifth and Eleventh Circuits require a showing of a "substantial threat" of harm. *E.g. Palmer v. Braun*, 287 F.3d 1325, 1329 (11th Cir. 2002). The Tenth and D.C. Circuits require a showing of "substantial likelihood" of success on the merits. *E.g. Kikumura v. Hurley*, 242 F.3d 950, 955 (10th Cir. 2001); *Al-Fayed v. CIA*, 254 F.3d 300, 303 (D.C. Cir. 2001); *Walgreen*, 275 F.3d at 477. The Fourth and Sixth Circuits require only a "likelihood" of success. *E.g. Safety-Kleen, Inc. v. Wyche*, 274 F.3d 846, 858-59 (4th Cir. 2001); *County Sec. Agency v. Ohio Dep't of Commerce*, 296 F.3d 477, 485 (6th Cir. 2002). And other circuits require a "probability" of success on the merits. *E.g. Entergy, Ark., Inc. v. Nebraska*, 210 F.3d 887, 898 (8th Cir. 2000).

Other circuits have adopted two-part balancing tests that incorporate most of the equitable factors. The Second Circuit requires an alternative showing of (1) irreparable harm, and (2) either a likelihood of success on the merits or sufficiently serious questions going to the merits to make them a fair ground for litigation, in addition to a balance of hardships that tips decidedly toward the movant. *E.g. Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.*, 596 F.2d 70, 72 (2d Cir. 1979) (per curiam). The Ninth Circuit requires either "(1) a combination of probable success on the merits and the possibility of irreparable harm; or (2) that serious questions are raised and the balance of hardships tips in its

favor." *E.g. Sammartano v. First Judicial District Court*, 303 F.3d 959, 965 (9th Cir. 2002) (internal quotation and citation omitted).

B. The Federal Circuit's Fixation Upon Whether A "Clear Case" Of Validity Has Been Shown Is Improper.

The different standards used throughout the various circuits have created confusion throughout the judiciary. Some clarity is possible if the Court were to hold that the Federal Circuit cannot transform appellate review of preliminary injunctions into a mini-trial on a single merits question. Requiring plaintiffs to present a "clear case" of patent validity, *Amazon.Com*, 239 F.3d at 1359, and then focusing appellate review entirely upon that question to the exclusion of the traditional bases for a preliminary injunction places an unwarranted burden on patent holders seeking to show a likelihood of success on the merits, and undercuts the presumption of validity to which all patents are entitled.

Because the Federal Circuit has exclusive jurisdiction over patent appeals, this novel requirement governs all patent preliminary injunction cases in the United States. Because this error devalues, and continues to devalue, the presumption of validity entitled to all patents, the error should not stand uncorrected. *See Cardinal Chem. Co. v. Morton Int'l Inc.*, 508 U.S. 83, 89 (1993). In reviewing that error, the Court can re-affirm and clarify that a preliminary injunction proceeding and appellate review of that proceeding is not a substitute for trial on the merits.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for writ of *certiorari*.

Respectfully submitted,

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CONTENTS

Document	Page
Opinion, United States Court of Appeals for the Federal Circuit (Nov. 17, 2004)	1a
Order, United States Court of Appeals for the Federal Circuit (Dec. 17, 2004)	12a
Memorandum Opinion, United States District Court for the District of New Jersey (Mar. 1, 2004)	13a

UNITED STATES COURT OF APPEALS, FEDERAL CIRCUIT

MEDPOINTE HEALTHCARE INC.,
Plaintiff-Appellee,
v.
HI-TECH PHARMACAL CO., INC.,
Defendant-Appellant.
No. 04-1310.

Decided: Nov. 17, 2004.
Rehearing Denied Dec. 17, 2004.

Before MAYER, Chief Judge, SCHALL, and PROST, Circuit Judges.

Opinion for the court filed by Circuit Judge PROST.
Dissenting opinion filed by Chief Judge MAYER.

PROST, Circuit Judge.

Hi-Tech Pharmacal Co. ("Hi-Tech") appeals a preliminary injunction granted by the United States District Court for the District of New Jersey to plaintiff Medpointe Healthcare Inc. ("Medpointe") in regard to the sale and manufacture of a pharmaceutical composition protected by United States Patent No. 6,417,206 ("the '206 patent"). Because Medpointe has not shown Hi-Tech's invalidity defense based on obviousness is without substantial merit, we vacate the preliminary injunction.

BACKGROUND

MedPointe brought suit against Hi-Tech for allegedly infringing the '206 patent. The '206 patent claims therapeutic compositions of a pharmaceutical drug containing three active ingredients: (1) carbetapentane tannate, (2) pyrilamine tannate,

and (3) phenylephrine tannate.[1] Hi-Tech is a generic drug company that manufactures the same claimed composition. It does not dispute that its generic version of the drug infringes the '206 patent, but asserts in its defense that the patent is invalid for obviousness under 35 U.S.C. § 103. In this appeal, Hi-Tech argues that the district court erred in concluding that it had not raised a substantial question of validity of the '206 patent. Hi-Tech contends that a pharmaceutical composition, named "Candettes,"[2] either alone or in combination with other prior art, such as Medpointe's Tussi-12 product,[3] renders the claims of the '206 patent obvious. The Candettes product, which has been available to the public since 1938, contains the same three types of active molecules claimed by the '206 patent, but has associated with each type of active molecule a different salt counterion than that claimed by the '206 patent. According to Hi-Tech, it would have been obvious to substitute tannate for the counterions in Candettes. Alternatively, Hi-Tech contends that it would have been obvious to modify the prior art, by substituting, for example, pyrilamine tannate for chlorpheniramine tannate in Medpointe's Tussi-12 product. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

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[1] The sole independent claim in the patent reads as follows:

> 1. A therapeutic composition for the symptomatic relief of cough associated with adverse respiratory tract conditions in warm-blooded animals in need of such treatment said composition comprising pharmaceutically effective amounts of active ingredients, wherein said active ingredients consist of carbetapentane tannate, pyrilamine tannate and phenylephrine tannate.

[2] Candettes contains carbetapentane citrate, phenylephrine hydrochloride, and pyrilamine maleate.

[3] Tussi-12 contains carbetapentane tannate, phenylephrine tannate, and chlorpheneramine tannate.

DISCUSSION

I. STANDARD OF REVIEW

"[T]his court reviews a district court's decision granting, denying, or modifying an injunction, in a patent case ... applying Federal Circuit law." *Int'l Rectifier Corp. v. Samsung Elecs. Co.*, 361 F.3d 1355, 1359 (Fed. Cir. 2004); *see also Lab. Corp. of Am. Holdings v. Chiron Corp.*, 384 F.3d 1326, 1331 (Fed. Cir. 2004) (recognizing the Federal Circuit's precedent of reviewing the grant or denial of an injunction directed to substantive issues in patent cases under Federal Circuit law). We review the grant or denial of a preliminary injunction by a district court for abuse of discretion. *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1367 (Fed. Cir. 1996). "An abuse of discretion may be established by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1359 (Fed. Cir. 2001) (quoting *Novo Nordisk*, 77 F.3d at 1367).

Medpointe is entitled to a preliminary injunction only if it can carry its burden of showing: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest. *Id.* at 1350. Although in some circumstances these factors taken individually may not be dispositive because the district court's decision to grant or deny a preliminary injunction rests on an overall process of balancing, a preliminary injunction cannot be granted if the movant is unable to show a reasonable likelihood of success on the merits. *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1325 (Fed. Cir. 2004). To succeed at demonstrating the likelihood of success, Medpointe must present a "clear case" supporting the validity of the patent in suit, thus showing that Hi-Tech's invalidity defense lacks substantial merit. *Amazon.com*, 239 F.3d at 1359. Hi-Tech

may defeat the motion for a preliminary injunction by showing that the patent is "vulnerable" to attack based on validity. *Id.*

II. ANALYSIS

A.

Hi-Tech relies on Candettes, which was not before the Patent and Trademark Office ("PTO"), as the primary reference that allegedly renders the claims of the '206 patent obvious. Hi-Tech contends that Candettes provides the requisite teaching that it would be desirable to combine salts of carbetapentane, pyrilamine, and phenylephrine, and that reference, either alone or in combination with Tussi-12, renders obvious the tannate composition defined by claim 1 of the '206 patent. Hi-Tech complains that the district court erroneously determined that ammonium chloride, which Candettes lists as one of its ingredients, is an active ingredient that must be removed, among other things, to transform Candettes into the composition defined by the claims of the '206 patent. Further, Hi-Tech argues that the court effectively ignored Candettes in addressing the incentive to combine prior art. In addition, the district court allegedly made a legal error by erroneously requiring an explicit teaching to combine the three active ingredients claimed by the '206 patent, thereby effectively requiring anticipation by the prior art to raise a substantial question of invalidity based on obviousness, and mischaracterizing Hi-Tech's arguments as "obvious to try." Further, Hi-Tech argues that the district court erred in regard to a number of factual findings that allegedly should not have weighed in favor of finding the '206 patent nonobvious, including (1) the difficulty of working with tannates as a disincentive to combine prior art products, (2) the patented invention's commercial success, (3) the copying by Hi-Tech after MedPointe released its product, and (4) the failure of others to formulate or market an anticipatory pharmaceutical composition before the '206 patent. As to the other preliminary injunction factors, Hi-Tech asserts that the district court erred

in finding that MedPointe would be irreparably harmed without an injunction.

B.

The parties' principal dispute revolves around the district court's scrutiny of Candettes. For the reasons that follow, we find that the district court clearly erred in concluding that ammonium chloride must be removed to place Candettes within the scope of the claims of the '206 patent. In addition, we find that the district court clearly erred in its assessment of evidence concerning a teaching or motivation to modify Candettes by replacing the counterion associated with each active ingredient with a tannate. Lastly, the district court erred in its weighing of the evidence of secondary considerations against the evidence of incentive to modify Candette. These errors mandate that we vacate the district court's preliminary injunction. We discuss the errors in greater detail below.

1.

Although claim 1 uses open-ended, i.e., "comprising," language to permit pharmaceutically acceptable inactive ingredients to be a part of the claimed therapeutic composition, it limits the range of active ingredients to only carbetapentane tannate, pyrilamine tannate and phenylephrine tannate. Because the district court held that the ammonium chloride must be removed as part of the transformation to place Candettes within the scope of the composition defined by claim 1, the court evidently assumed that ammonium chloride is an active ingredient. Neither the district court nor Medpointe, however, cite any record evidence to support the assumption or to rebut Hi-Tech's expert, who testified that ammonium chloride is an inactive ingredient. Medpointe contends that Hi-Tech's testimony should be disregarded because its expert did not testify "how one of ordinary skill would interpret the Candettes reference." Alternatively, Medpointe argues that we should infer that ammonium chloride is active merely because

it is listed in a specific quantity on the specification sheet for the Candettes product.

After careful review of the record evidence proffered by Medpointe in its briefs and at oral argument, we discern no reasonable basis for the court's implicit factual finding that ammonium chloride is an active ingredient that must therefore be removed to transform Candettes into the composition claimed by the '206 patent. In view of the uncontroverted testimony from Hi-Tech's expert that ammonium chloride is inactive, the court's factual determination to the contrary is unsupported and thus clearly erroneous.

2.

Operating under the false premise that a suggestion or motivation must be found to remove the ammonium chloride for Candettes to read on the claims of the '206 patent, the district court determined that it was "far more likely for a practitioner to have discerned a suggestion or motive in the prior art to add an anti-tussive to Ryna-12 or the '597 composition" than to modify Candettes.[4] Notwithstanding the erroneous factual finding in regard to ammonium chloride that underlies the court's preliminary injunction, Medpointe maintains that the injunction may still stand. Medpointe asserts that any incentive to undertake the exchange of salts to make the tannate version of Candettes would have been counteracted by the knowledge that tannate salts are difficult to work with and present significant formulation problems at high levels.

The district court, in agreement with Medpointe, found "it is difficult for practitioners of ordinary skill to work with tannates," and "a practitioner would thus not have been inclined to experiment with them barring external reason for doing so." The district court appeared, however, to unduly discount other

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[4] Ryna-12 and the '597 composition (United States Patent No. 6,287,597) contain both phenylephrine tannate and pyrilamine tannate.

evidence in the record, which weighs in favor of finding that there was indeed incentive to modify Candettes to attain the composition claimed by the '206 patent. In particular, the court found that tannates were "well-known to ordinarily skilled practitioners" and that such practitioners would know tannate salts are useful as a way to provide longer-lasting dosages of pharmaceuticals to a person. Further, the record shows that the three active ingredients found in Candettes were each previously converted with success from a non-tannate to a tannate salt, demonstrating that the barriers imposed by working with tannates were in fact not insurmountable or so great as to deter those skilled in the art from undertaking the conversion. Moreover, the evidence shows that each of the active ingredients found in Candettes was successfully used in the tannate form, often in combination with the tannate versions of one of the other active ingredients present in Candettes. Medpointe submits no evidence to suggest that any person skilled in the art expected the tannate version of the three active ingredients in Candettes would not work together. Perhaps most importantly, the inventors of the '206 patent admitted in the Background of Invention section of their patent that at the time of invention it was at least somewhat accepted that "[a]ntitussives, antihistamines, and decongestants in the form of their tannate salts are very desirable because such salts are generally stable and may be combined in such form without any untoward side effects." '206 patent, col. 1, l. 63--col. 2, l. 2 (emphasis added). The statement from the '206 patent appears to acknowledge the presence of an existing motivation to undertake the salt conversion that the district court evidently deemed missing from the record evidence. Thus, the court clearly abused its discretion when it failed to give weight to the significance of this professed motivation in its scrutiny of Candettes.

3.

As for evidence of secondary considerations, we find them insufficient to show that the defendant's invalidity defense based on Candettes is without substantial merit. Evidence of secondary considerations, such as failure of others, unexpected results, long felt but unresolved need, commercial success, and copying, is often probative in the obviousness analysis. *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1274 (Fed. Cir. 2004). Here, the district court did not find evidence of failure of others or unexpected results. Moreover, the court opined that "[i]t was unclear whether the '206 patent fulfills any 'long felt need.'" Although the district court found that Medpointe had demonstrated the commercial success of its claimed composition (marketed as Tussi-12D), the purported commercial success is somewhat tenuous given that Medpointe's product has so far only broken even in the amount of money made, with the product's long-term profitability yet to be established. The weak evidence of commercial success and copying by competitors is inadequate to demonstrate nonobviousness of the claimed invention in view of the substantial question of validity raised by Candettes and the strong desirability professed by the '206 patent to use antitussives, antihistamines, and decongestants in their tannate form.

CONCLUSION

We conclude that the district court erred in failing to recognize that Candettes raises a substantial question of invalidity.[5] Because Medpointe has not shown Hi-Tech's

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[5] Our decision today on the validity issue in no way resolves the ultimate question of invalidity. It remains to be determined in what way any shortcomings in Hi-Tech's initial preliminary validity challenge will be developed with further fact finding. We hold at this juncture only that Hi-Tech has cast enough doubt on the validity of the '206 patent to avoid a preliminary injunction.

obviousness defense lacks substantial merit, Medpointe has failed to carry its burden of showing it will likely prevail on the merits at the final hearing. Accordingly, we must conclude that a necessary prerequisite for entry of a preliminary injunction is absent. We therefore vacate the preliminary injunction.[6]

MAYER, Chief Judge, dissenting.

Based on the evidence and keeping in mind the proper role of an appellate court, I would affirm the district court's decision to maintain the status quo pending a resolution of Medpointe's allegation of infringement. There are three major flaws in this court's opinion. First, the court overturns the district court's finding that ammonium chloride is an active ingredient in the Candettes formulation. The court bases this determination on a single statement by Hi-Tech's expert witness James O'Donnell: "Ammonium Chloride, however, is an inactive ingredient." The court apparently believes that this evidence is particularly weighty because Medpointe failed to rebut it with expert testimony. O'Donnell's testimony, however, is conclusory and unsupported. Further, the district court also considered the Candettes reference, which itself provides compelling evidence that ammonium chloride is an active ingredient. The reference lists only four ingredients: carbetapentane citrate, pyrilamine maleate, phenylephrine hydrochloride and ammonium chloride. The precise amount of ammonium chloride is specified in a manner similar to that of the other three ingredients. And, the Candettes reference conspicuously fails to list any of the inactive ingredients that are required for a preparation of this type. If ammonium chloride is an inactive ingredient, why does the Candettes reference list it but fail to list any others? The

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[6] Because we find that Medpointe has failed to show it will likely prevail on the merits, as required, to warrant issuance of the preliminary injunction, we find it unnecessary to address the alleged errors by the district court in regard to the irreparable harm finding.

district court, which has special expertise in making credibility determinations, was entitled to disregard O'Donnell's testimony, especially in light of the Candettes reference. *See Rohm and Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997) ("Nothing in the rules or in our jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness."); *see also Libas, Ltd. v. United States*, 193 F.3d 1361, 1366 (Fed. Cir. 1999) ("It would make little sense to say that a trial court in its fact-finding role should accord much if any weight to expert testimony, the reliability of which is not established."). Consequently, this court's decision that ammonium chloride is an inactive ingredient required the reversal of a credibility determination in addition to a reweighing of the evidence. Such a foray into the virtually exclusive province of the district court has been regularly and consistently criticized by both the Supreme Court and this court. *See, e.g., Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 122 n.18 (1969) ("Rule 52(a) admonishes due regard for the trial court's opportunity to assess the credibility of witnesses."); *Applied Med. Res. Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 1379 (Fed. Cir. 1998).

The court then disputes the district court's determination that tannates are difficult to work with. In so doing, it takes issue with the district court's failure to properly weigh the evidence. This court apparently feels that because tannates are both "well-known to ordinarily skilled practitioners" and long-lasting, *ante*, at 80, the district court could not have found that tannates are difficult to work with. The district court, however, was also presented with evidence in the testimony of Dr. D'Addio that the volume of tannates in the '206 formulation exceeded any other previous preparation and that such a high concentration presented increased difficulty. Presented with this testimony, which the district court obviously credited, it is hard to see how this court was "left with the definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948).

Finally, this court found that the "commercial success [of Tussi-12D] is somewhat tenuous given that Medpointe's product has so far only broken even," and that the evidence of copying is weak. *Ante*, at 81-82. I have been unable to find any case that suggests that a product was commercially unsuccessful because it had only broken even at the time of inquiry. Tussi-12D has been on the market since 2002, barely enough time to have recouped the investment in R & D that was necessary for its development. At the time the district court's opinion was written, Medpointe had already sold in excess of $14 million worth of Tussi-12D. Further, no fewer than four companies are poised to flood the market with generic formulations of the '206 patent. Based on this evidence, it is hard to imagine that Tussi-12D has not been greeted favorably by consumers. Because I cannot join in the court's de novo review of the district court's findings of fact, I respectfully dissent.

ORDER

Before MAYER, Chief Judge, SCHALL, Circuit judge, and PROST, Circuit Judge.

A petition for rehearing having been filed by the APPELLEE,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED.

The mandate of the court will issue on December 27, 2004.

FOR THE COURT,

__/s/_____
Jan Horbaly
Clerk

Dated: December 17, 2004

cc: William L. Mentlik
Peter J. Armenio

MEDPOINTE HEALTHCARE V HI-TECH PHAR, 04-1310 (DCT - 3:03-CV-05550)

Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MEDPOINTE HEALTHCARE INC.,	:	
	:	CIVIL ACTION NO. 03-5505 (MLC)
Plaintiff,	:	
	:	
v.	:	**MEMORANDUM OPINION**
PRASCO, LLC, d/b/a PRASCO LABORATORIES,	:	
	:	Filed March 1, 2004
Defendant.	:	
	:	
MEDPOINTE HEALTHCARE INC.,	:	
Plaintiff,	:	CIVIL ACTION NO. 03-5550 (MLC)
v.	:	**MEMORANDUM OPINION**
HI-TECH PHARMACAL CO., INC.,	:	
Defendant.	:	

This matter comes before the Court on two motions by plaintiff, MedPointe Healthcare Inc. ("MedPointe"), respectively seeking preliminary injunctive relief against defendants, Prasco LLC, d/b/a Prasco Laboratories ("Prasco") and Hi-Tech Pharmacal Co., Inc., ("Hi-Tech"), to stop each from marketing in the United States generic copies of the

prescription anti-cough medication MedPointe sells under the trade name "Tussi 12-D."

MedPointe possesses the exclusive rights to U.S. Patent No. 6,417,206 ("the `206 patent"). MedPointe contends that the defendant's prospective products, *i.e.*, Prasco's "C-Tanna 12D" and Hi-Tech's "Tannate-12DS", infringe the `206 patent and that a preliminary injunction should be entered against both Prasco and Hi-Tech.

Both defendants oppose the injunction by arguing that a substantial question exists as to the validity of the '206 patent on the ground of obviousness. Hi-Tech further argues that a substantial question exists as to the enforceability of the '206 patent due to MedPointe's alleged inequitable conduct before the Patent and Trademark Office ("PTO"). Hi-Tech, however, concedes that if the Court finds the '206 patent to be both valid and enforceable, Hi-Tech's conduct infringes the patent.

Prasco does not concede infringement. It alleges that its C-Tanna 12D contains an extra intended "active ingredient." It thus argues that its product falls outside the scope of the `206 patent. Moreover, Prasco alleges that MedPointe cannot show any real danger of irreparable harm because MedPointe's Tussi 12-D itself contains an extra and undisclosed active ingredient not mentioned in the '206 patent, putting Tussi 12-D beyond the patent's scope.

The Court has considered the papers submitted by the parties and heard oral argument and witness testimony from December 22 to 24, 2003.[1] The Court hereby issues its findings of fact and

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[1] The Local Civil Rules of this district provide that all motion papers except briefs are filed on the docket. Some papers were submitted under seal. Portions of the testimony were closed to the public under a protective order issued on 12-22-03.

MedPointe's motion is brought under two separate docket numbers: CV 03-5505 against Prasco and CV 03-5550 against Hi-Tech. The cases have not been consolidated, although both were addressed at the same preliminary injunction hearing on December 22, 23, and 24, 2003. Docket notations in

conclusions of law as required by Federal Rule of Civil Procedure ("Rule") 52. For the reasons given in this Memorandum and Order, we conclude that MedPointe has met its burden of demonstrating its right to injunctive relief. Therefore, upon posting of an appropriate bond both motions will be granted pursuant to Rule 65.

I. BACKGROUND

A. The '206 Patent, the Parties and their Products

MedPointe is a New Jersey corporation headquartered in Somerset, New Jersey that develops, markets and sells branded prescription pharmaceuticals. (Edick Hi-Tech Decl. ¶ 3; *see* P-

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the Prasco action will be referred to as "05-[no.]". Docket notations in the Hi-Tech action will be referred to as "50-[no.]".

The record is as follows: MedPointe's brief in support of injunctive relief against Prasco (11-21-03) ("Pl. Pr. Br."); MedPointe's brief in support of injunctive relief against Hi-Tech (11-25-03) ("Pl. Hi. Br."); Prasco's opposition brief (12-15-03) ("Prasco Br."); Hi-Tech's opposition brief (12-16-03) ("Hi-Tech Br."); MedPointe's reply brief against Prasco (12-22-03) ("Reply to Prasco Br."); MedPointe's reply brief against Hi-Tech (12-22-03) ("Reply to Hi-Tech Br."); transcript of 11-21-03 TRO hearing ("11-21-03 Tr.") (05-08); transcripts of preliminary injunction hearing ("12-22-03 Tr."; "12-23-03 Tr."; "12-24-03 Tr.").

MedPointe's supporting documentation includes: Verified Complaints ("Prasco Compl." & "Hi-Tech Compl.") (05-01 & 50-01); declaration of Paul R. Edick against Prasco ("Edick Pr. Decl.") (05-22); declaration of Paul R. Edick against Hi-Tech ("Edick Hi-Tech Decl.") (50-04); declaration of Irving W. Wainer against both defendants ("Wainer Decl.") (05-21); transcript of 12-17-03 deposition of Prasco's Rule 30(b)(6) witness, Glenn S. Vraniak ("Vraniak Tr."); transcript of 12-17-03 deposition of Hi-Tech's Rule 30(b)(6) witness, David Seltzer ("Seltzer Tr."); exhibits admitted at preliminary injunction hearing ("P-[no.]").

Prasco's supporting documentation includes: declaration of H. Greg Thomas ("Thomas Decl.") (05-16); exhibits admitted at preliminary injunction hearing ("PR-[no.]").

Hi-Tech's supporting documentation includes: affidavit of James O'Donnell ("O'Donnell Aff.") (50-10); exhibits admitted at preliminary injunction hearing ("D-[no.]").

221.) It was known as Carter-Wallace, Inc., until October 2001. (Edick Hi-Tech Decl. ¶ 1.)

MedPointe is the owner-assignee of the '206 patent, which was issued on July 9, 2002.[2] (P-2; *see* 12-22-03 Tr. at 77.) It is due to expire on January 26, 2021. (Edick Hi-Tech Decl. ¶ 18.) The '206 patent is directed to a certain combination of pharmaceuticals to be administered "for the symptomatic relief of cough." (P-2, Abstract & Claim 1.) The composition's listed "active ingredients" are: an anti-tussive, carbetapentane tannate; an antihistamine, pyrilamine tannate; and, a decongestant, phenylephrine tannate. (*Id.*, Abstract, Specification ("Spec.") & Claim 1.)

The "active form" of each of these drugs has been used for decades.[3] (Repoza Testimony, 12-22-03 Tr. at 205-07; O'Donnell Testimony, 12-24-03 Tr. at 17-18.) The '206 patent itself states, for example, that pyrilamine is "one of the oldest and most enduring anti-histaminic drugs." (P-2, Col. 1, Lines 41-42; *see* PR-10.) The age and long-standing reputation of each of these drugs was such that MedPointe was not required to seek FDA approval of Tussi-12D, its commercial embodiment of the '206 patent, before releasing it.[4] (Edick

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[2] A true copy of the '206 patent is attached as an exhibit to various filings. This opinion will refer to it as the `206 patent and will cite it under its hearing exhibit number, P-2. Citation to column and line references is provided as needed.

[3] The "active form" refers to the pharmaceutically-active base, or "free base." It is combined with one of a variety of acids, resulting in a "salt." Carbetapentane base, for example, when combined with citric acid, forms carbetapentane citrate, and so on. (Repoza Testimony, 12-22-03 Tr. at 216-17.)

[4] Each of Tussi 12-D's active pharmaceutical components is a grandfathered "DESI" drug, *i.e.*, recognized by the FDA as safe for human use before its current approval process began in 1962. (Edick Testimony, 12-23-03 Tr. at 207-08.) DESI stands for "Drug Efficacy Safety Implementation." (Repoza Testimony, 12-22-03 Tr. at 232.)

Testimony, 12-23-03 Tr. at 207-08.) MedPointe did not clinically test Tussi-12D before its release. (D'Addio Testimony, 12-23-03 Tr. at 53-57.)

The asserted innovation of the '206 patent is the combination of each of the tannate salt forms of each listed drug, *i.e.*, the resulting compound of each drug's active form with tannic acid (P-2, Cols. 1 & 2.) Such a combination "in the form of their tannate salts [is] very desirable because such salts are generally stable and may be combined in such form without any untoward side effects." (*Id.*, Col. 1, Line 67 to Col. 2, Line 2.) Tannate salts are medically desirable because their limited solubility means that they are absorbed slowly. (O'Donnell Testimony, 12-24-03 Tr. at 35, 53-55; D'Addio Testimony, 12-23-03 Tr. at 66-67.) Tannate salt pharmaceuticals, even when administered in a suspension form, thus have a long and sustained effect. (O'Donnell Testimony, 12-24-03 Tr. at 32-35; *see* O'Donnell Aff. ¶ 16.) Tussi-12D, the embodiment of the '206 patent, for example, is to be administered once every twelve hours. (Wainer Testimony, 12-22-03 Tr. at 102; *see* O'Donnell Aff. ¶ 16.)

One of MedPointe's specialties is in the "cough/cold area." (Edick Hi-Tech Decl. ¶ 3.) It had marketed, as Carter-Wallace, a succession of cough/cold medications composed of various tannate salt combinations. (D-8; D-10.) Two predecessors to Tussi-12D, Tussi-12 and Tussi-12 (Reformulated), had chlorpheniramine tannate as an antihistamine instead of pyrilamine tannate. (D-8; *see* Repoza Testimony, 12-22-03 Tr. at 205-13.) Tussi-12 was otherwise composed of the same active components, administered in the same dosages, as Tussi-12D. (O'Donnell Testimony, 12-24-03 Tr. at 19-29.)

One inventor-assignor of the '206 patent is Alexander D'Addio, Ph.D., now Vice President of Product Development at MedPointe. D'Addio testified that he first had the idea to update the-then Wallace Laboratories's existing product line in Spring 2000. (D'Addio Testimony, 12-23-03 Tr. at 11-12.)

After some discussions that summer with the Marketing Department, he received a memo in November 2000 stating that the company wanted to try to "substitut[e] an equivalent dose of pyrilamine tannate for the present chlorpheniramine tannate dose [in Tussi-12]." (D-7; *see* D'Addio Testimony, 12-23-03 Tr. at 12-15.) D'Addio testified that tannate salts are not easy to work with, but that he and his colleague, Ronald Leflein, co-inventor-assignor on the '206 patent, eventually overcame their difficulties in developing a workable formulation. (*Id.* at 19-23; *see* P-88; P-92.) There was still, however, "extensive work" to be done throughout 2001 and much of 2002 in preparing the composition for final commercial release.[5] (D'Addio Testimony, 12-23-03 Tr. at 24; *see* P-90; P-91.)

The PTO issued the '206 patent on July 9, 2002. (P-2.) MedPointe commercially released Tussi-12D as a suspension that September and as a tablet by December. (D'Addio Testimony, 12-23-03 Tr. at 26-28; *see* Edick Testimony, 12-23-03 Tr. at 209-10; P-63; P-125.) MedPointe then registered Tussi-12D with the FDA, as required, the following April. (P-78; P-79; *see* Edick Testimony, 12-23-03 Tr. at 207-08.) Paul R. Edick, MedPointe's-President, claimed that his company received an "outstanding response" to the new product. (*Id.* at 208-09; *see* P-82.) He denied that the success of Tussi-12D lay in MedPointe's withdrawing Tussi-12 or in no longer supporting Tussi-12 (Reformulated). (Edick Testimony, 12-23-03 Tr. at 225-26, 245-48; *see* P-45; P-82.) He stressed that MedPointe had made a business decision to support Tussi-12D, that the wisdom of this decision was reflected in its resulting

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[5] D'Addio noted, however, that after the January 26, 2001 submission of the '206 patent application, he was not involved in MedPointe's negotiations with the PTO. (D'Addio Testimony, 12-23-03 Tr. at 52-53.) Conversely, Dr. Polireddy Dondeti, Senior Director of R & D at Hi-Tech, testified that he experienced few difficulties in working with tannates and producing a marketable generic version of Tussi-12D when he worked for Morton Grove Pharmaceuticals. (Dondeti Testimony, 12-23-03 Tr. at 273-77.)

positive sales, and that the company would continue to support and defend its innovations in a competitive but fair marketplace. (Edick Testimony, 12-23-03 Tr. at 233-35, 248-49.)

MedPointe favored promoting Tussi-12D over its predecessor products because of the competition the latter faced from generics. MedPointe's sales for each such drug had dropped dramatically as the market for each drug became "genericized" in the months after generic drug companies were able to enter the commercial fray. (*Id.* at 221-26; *see* P-86; P-223; P-224; P-225.) MedPointe was thus alarmed when it learned that some of its competitors were "linking" generic versions to Tussi-12D within the electronic databases, such as the "First Data Bank," used to order drugs. (Edick Testimony, 12-23-03 Tr. at 213-16; *see* P-73; P-93; P-94; P-95; P-222.) MedPointe was especially concerned because, once such a link was made, chain stores and other prospective buyers would prefer, or even be required, to buy the cheaper generic versions of Tussi-12D. (Edick Testimony, 12-23-03 Tr. at 213-16.) MedPointe thus took legal action.[6] (*Id.* at 216-19; *see* P-59; P-75.)

Prasco is one such competitor, and plans to distribute its generic as C-Tanna 12D. (*See* Vraniak Tr. 21-31; P-3; P-6.) This drug was formulated and manufactured for Prasco by Kiel Laboratories ("Kiel") according to Prasco's specifications, and

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[6] One competitor, Breckenridge Pharmaceutical, Inc., has already settled with MedPointe, signing a Consent Judgment that was filed on October 7, 2003. (P-75; *see* P-72; Edick Testimony, 12-23-03 Tr. at 216-17.) In it, Breckenridge stipulated to its infringement of the `206 patent, allowing a permanent injunction to be entered against it barring it from further infringement.

Another would-be competitor, Morton Grove Pharmaceuticals, has agreed with MedPointe to refrain from infringing the `206 patent until this Court decides the present motions or January 7, 2004, whichever comes first. (P-59.)

was ready to be shipped to purchasers when the Court entered temporary injunctive relief.[7] (Vraniak Tr. at 45-50, 82-96.) Kiel's Vice President of Research and Development, H. Greg Thomas, Ph.D., testified that Kiel produces C-Tanna 12D using a proprietary process it hopes to patent called "Tannate Conversion Technology" ("TCT"). (Thomas Testimony, 12-23-03 Tr. at 110-32; *see* P-96; P-97.)

Thomas testified that C-Tanna 12D differs from Tussi-12D in that the former has, as both starting ingredient and intended final component, a fourth active ingredient: phenylephrine hydrochloride, a second decongestant. (Thomas Testimony, 12-23-03 Tr. at 119-30, 156, 192-95.) He asserted that he not only confirmed this difference through his independent analysis of the Kiel product, but that his similar testing of MedPointe's product revealed that Tussi-12D itself had more than trace amounts of a non-tannate soluble form of phenylephrine, despite its label and the '206 patent. (*Id.* at 132-58; Thomas Decl. ¶¶ 4-7; *see* PR-22; PR-23; PR-27; P-400.) Leaving aside the validity of his testing methodology, *see infra* § II.C.(2)(a), Thomas could not explain why neither the patent applications for the TCT process nor the C-Tanna 12D and Viravan-DM package inserts failed to mention phenylephrine hydrochloride as an intended resulting component. (Thomas Testimony, 12-23-03 Tr. at 183-88; *see* P-3; P-6; P-96; P-97; P-99.)

Kiel did not inform Prasco of the presence of phenylephrine hydrochloride in C-Tanna 12D until this litigation began. (Thomas Testimony, 12-23-03 Tr. at 166-67.) Prasco admitted that neither its product insert nor its submissions to the databases linking its product to Tussi-12D included any references to the presence of phenylephrine hydrochloride in C-Tanna 12D. (Vraniak Tr. at 21-45, 114-22.) Prasco CFO

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[7] MedPointe has also filed a complaint with the Court alleging infringement of the '206 patent by Kiel in the action *MedPointe Healthcare v. Kiel Labs.*, 03-CV-5576. (See P-62.)

Glenn S. Vraniak stated at his Rule 30(b)(6) deposition for Prasco that the company did not know whether it planned on changing the product inserts or alerting pharmacists and the public to the presence of C-Tanna 12D's fourth active ingredient. (*Id.* at 21-45.) At the injunction hearing, however, he testified that Prasco had since begun internal consultations and would re-label and de-link its product from Tussi-12D if it determined that doing so "would be appropriate." (Vraniak Testimony, 12-23-03 Tr. at 266-67.)

Hi-Tech is another prospective competitor of MedPointe and plans to manufacture and distribute its generic as Tannate-12DS. (*See* Seltzer Tr. at 8-26.) CEO David Seltzer stated at his Rule 30(b)(6) deposition for Hi-Tech that his company had known about the '206 patent at the formulation stage of making its generic suspension, which has the same component actives in the same dosage amounts as Tussi-12D. (*Id.* at 41-44.) Tannate-12DS was intended "to have the exact same active ingredients in the exact amounts of the product they are seeking to copy." (*Id.* at 145.) Hi-Tech had represented its product as a substitute for Tussi-12D, had received some 7,000 orders and was ready to ship when the Court entered temporary restraints. (*Id.* at 89-124.)

Edick testified that MedPointe's losses, should Tussi-12D be genericized, would be dire. The '206 patent enables MedPointe to actively support Tussi-12D within the cough/cold medicine market, given the competitiveness therein. (Edick Testimony, 12-23-03 Tr. at 220, 229-32, 238-40.) He admitted that the data necessary for compensating MedPointe is conceivably available assuming that each sale of a generic version of Tussi-12D comprises a lost sale by MedPointe. (*Id.* at 235-38.) He asserted, however, that the company's potential losses are not readily compensable or even quantifiable because Tussi-12D's genericization threatens the continued viability of MedPointe as a company. (*Id.* at 225-28.) At the very least, genericization threatens its ongoing R & D budget. (*Id.* at 254.) Edick

asserted that MedPointe has never granted a license under the '206 patent, has no intention of doing so, and has the ability to fully supply the available market for Tussi-12D. (*Id.* at 220-21; *see* Edick Pr. Decl. ¶ 8.)

B. The Present Litigation

MedPointe filed separate Verified Complaints, one against Prasco on November 21, 2003, and one against Hi-Tech on November 25, 2003. (*See* Prasco Compl.; Hi-Tech Compl.) The Court entered an Order to Show Cause on November 21, 2003, temporarily restraining Prasco prior to a preliminary injunction hearing. (*See* 05-05.) The Court entered temporary restraints against Hi-Tech on December 1, 2003.[8] (*See* 50-06.) The hearing itself took place from December 22 to 24, 2003. (*See* 05-19; 50-14.) On the first day of the hearing, the Court entered a Protective Order closing portions of the testimony and sealing certain filings on the record. (*See* 05-15; 50-13.) The defendants have filed Answers, Prasco on December 9, 2003 and Hi-Tech on December 18, 2003. (*See* 05-09; 50-09.)

C. The Claims of the '206 Patent

The '206 patent is composed of fourteen claims, with only the first ("Claim 1") being independent. (P-2, Col. 4.) Claim 1 states:

> 1. A therapeutic composition for the symptomatic relief of cough associated with adverse respiratory tract conditions in warm-blooded animals in need of such treatment said composition comprising pharmaceutically effective amounts of active ingredients, wherein said active ingredients consist of carbetapentane tannate, pyrilamine tannate and phenylephrine tannate.

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[8] MedPointe was ordered to post an initial bond amount of $20,000 in each of the actions. (See Nos. 05-05 and 50-06.)

Claim 8 is a dependent method claim covering the administration of the composition in Claim 1. (*Id.*) Claims 2 through 4 address the composition in tablet form; 9 through 11, the method of administering same. (*Id.*) Claims 5 through 7 address the composition in suspension form; 12 through 14, the method of administering same.[9] (*Id.*)

[9] Dependent claims 4 and 11, and 7 and 14, respectively dealing with tablets and suspensions, address the dosages of the active ingredients: 60 mg and 30 mg/5 ml, carbetapentane tannate; 40 mg and 30 mg/5 ml, pyrilamine tannate; 10 mg and 5 mg/5 ml phenylephrine tannate. (P-2, Col. 4.) Dependent claims 3 and 10, and 6 and 13, respectively address the dosages of the actives characterized as ranges, with the middle generally being the same value given in the prior set of claims. (*Id.*)

D. The Prosecution File History of the '206 Patent

The application for the '206 patent was filed on January 26, 2001. (P-35 at 13-9.) [10] The patent prosecution concluded with a Notice of Allowability issued on April 23, 2002. (*Id.* at 91-94.) The patent was effective on July 9, 2002. (*Id.* at 9.) We will first present a brief chronological overview of the file history, and then cover the pertinent details.

As originally filed, the application contained six claims (two independent and four dependent claims). (*Id.* at 21, 28.) All six original claims were rejected in an Office Action dated May 4, 2001 ("First Office Action"). (*Id.* at 30-36.)

The applicant filed an amendment on August 20, 2001 ("First Amended Application"). (*Id.* at 41-52.) The First Amended Application cancelled the original six claims and inserted ten new claims. Only the first, claim 7, was independent. (*Id.* at 41-43.) The examiner conducted a telephone interview on November 11, 2001 ("First Interview"). (*Id.* at 53.) All ten claims in the First Amended Application were rejected in an Office Action dated November 15, 2001 ("Second Office Action"). (*Id.* at 54-59.)

Another amendment was filed on March 22, 2002 ("Second Amended Application"). (*Id.* at 62-82.) The Second Amended Application modified claim 7 and two of its dependent claims. It also added four new dependent claims, making a total of fourteen proposed claims. (*Id.* at 62-65.) The examiner conducted another telephone interview on April 17, 2002 ("Second Interview"). (*Id.* at 90.) On that same date, the applicant faxed and mailed to the examiner a Supplemental Statement that became an attachment to the examiner's

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[10] All citations in this section refer to the official Patent File History, hearing exhibit P-35. The pages of the document bear sequential numbers M 000004 through M 000095, which we will cite as pages 4-95.

summary of the Second Interview. (*Id.* at 83-89.) The examiner stated in the summary that agreement had been reached with respect to the claims. (*Id.* at 90.)

The Notice of Allowability, issued on April 23, 2002, allowed all fourteen of the claims contained in the Second Amended Application. (*Id.* at 91.) Thus, the claims formerly numbered 7-20 were renumbered and allowed as claims 1-14 of the '206 patent. (*Id.* at 7.)

We will now summarize the dialogue between the applicant and the PTO on the issue of obviousness. This portion will focus primarily upon the file history of claim 1 of the patent as issued (former claim 7), as it is the only independent claim.

(1) Original Application and First Office Action

The title and specification of the '206 patent are the same as in the original application.[11] The patent is entitled "Antitussive/Antihistaminic/Decongestant Compositions." (*Id.* at 9.) Original claim 1 stated:

> A therapeutic composition for the symptomatic relief of cough associated with respiratory tract conditions such as the common cold, bronchial asthma, acute and chronic bronchitis in warm-blooded animals in need of such treatment said composition comprising pharmaceutically effective amounts of carbetapentane tannate, pyrilamine tannate and phenylephrine tannate.

(*Id.* at 21.)

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[11] The examiner made only one alteration to the original specification, changing the location of the words "are disclosed" in the abstract. (*Compare id.* at 13 with *id.* at 9.) Note that in this section of the opinion, for ease of reference we will refer to the copy of the '206 patent that is contained in the Patent File History at pages 9-11.

The Background section of the specification describes carbetapentane as an antitussive compound that is described in an earlier patent, pyrilamine as "one of the oldest and most enduring antihistaminic drugs," and phenylephrine as a sympathomimetic amine. (*Id.* at 10.) It states that "[a]ntitussive, antihistamine and decongestant compounds in the form of their free bases as well as their salts, e.g. hydrochloride, citrate, maleate, tannate, etc., are well known...." and that "[a]ntitussives, antihistamines and decongestants in the form of their tannate salts are very desirable because such salts are generally stable and may be combined in such form without any untoward side effects." (*Id.*)

The Invention section of the specification states in pertinent part:

> It has now been found that the novel combination of carbetapentane tannate, pyrilamine tannate and phenylephrine tannate produces a composition having antitussive, antihistaminic and sympathomimetic decongestant properties superior to the use of any one of the tannate compounds alone.

(*Id.*)

The First Office Action rejected the original application on grounds of obviousness under 35 U.S.C. § 103(a), referring to a Japanese patent ("JP 64007786") and a journal article ("Weiler, et al."). (*Id.* at 31-36.) [12] On this point the examiner stated:

> Weiler teaches a therapeutic composition comprising pyrilamine tannate and phenylephrine tannate to provide symptomatic relief in the

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[12] The First Office Action also rejected claims 1 and 4 for indefiniteness pertaining to the ailments listed, but that problem was mooted by the First Amended Application and is not pertinent to the present discussion. (P-35 at 32, 41, 56.)

> treatment of allergic rhinitis, a respiratory condition. The Japanese document teaches a therapeutic composition comprising the cough suppressant carbetapentane tannate. The claims differ in that there is no suggestion in either of the references to link the specific ingredients. However, one skilled in the art would have been motivated to combine the three ingredients in a pharmaceutical composition to provide symptomatic relief of cough associated with respiratory tract conditions. Such would have been obvious in the absence of evidence to the contrary because it is generally *prima facie* obvious to use in combination two or more ingredients that have been used separately for the same purpose. *In re Kerkhoven* 205 USPQ 1069 (CCPA). Because the decongestant, antihistamine and cough suppressant are all tannates, there would have been a reasonable expectation of compatibility.

(*Id.* at 32-33.) [13]

(2) First Amended Application and Second Office Action

The First Amended Application, as stated above, cancelled the original six claims and inserted new independent claim 7 ("original claim 7"), along with nine dependent claims. (*Id.* at 41-43.) Original claim 7 stated:

> A therapeutic composition for the symptomatic relief of cough associated with adverse respiratory tract conditions in warm-blooded animals in need

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[13] Due to the volume of discussion in some of the cited portions of the prosecution history, this opinion quotes only the most pertinent portions. The reader is directed to the Patent File History for the surrounding portions of text.

> of such treatment said composition comprising pharmaceutically effective amounts of carbetapentane tannate, pyrilamine tannate and phenylephrine tannate.

(*Id.* at 42.)

The First Amended Application was accompanied by a brief in which the applicant argued against the obviousness rejection contained in the First Office Action, stating as follows:

> Original claims 1-6 stand rejected as obvious over Weiler et al. in combination with JP 64007786 (hereinafter "the Japanese reference"). Weiler et al. is stated to teach a therapeutic composition comprising pyrilamine tannate and phenylephrine tannate to provide symptomatic relief from of [sic] allergic rhinitis. The Japanese reference is stated to teach a therapeutic composition comprising the cough suppressant carbetapentane tannate.
>
> The Office Action admits that there is no suggestion in either of the references to link the specific ingredients. However, the Office Action states that one of ordinary skill in the art would have been motivated to combine the three ingredients to provide symptomatic relief of cough associated with adverse respiratory tract conditions....
>
> ....
>
> Weiler et al. discloses a double-blind test of the commercial product Rynatan which contains chlorpheniramine tannate, pyrilamine tannate and phenylephrine tannate. The test is administered to determine the effectiveness of Rynatan against allergic rhinitis. Rhinitis is defined as ....[N]othing in Weiler et al. or the dictionary reference indicates

that allergic rhinitis is associated with a cough sufficient to require an antitussive agent.

[I]t is ... submitted that one of ordinary skill in the art would not be lead [sic] to the claimed invention by the information provided in Weiler et al.

There is no teaching or suggestion in Weiler et al. of treating cough nor any suggestion that it is possible to combine an antitussive agent with any composition fairly disclosed in the Weiler et al. In addition, there is no teaching or suggestion that chlorpheniramine tannate as required in Weiler et al. should be eliminated from the composition nor any teaching that the composition can be provided with an antitussive agent (i.e. carbetapentane tannate)....

The addition of the Japanese reference does not cure the deficiencies of the primary reference. Applicants do not dispute that carbetapentane tannate was known as a cough-suppressor prior to the present invention. However, the mere existence of carbetapentane tannate as an antitussive agent does not lead one ... to eliminate chlorpheniramine tannate from the Weiler et al. composition and add another, materially different compound with an entirely different function (carbetapentane tannate)....

.... *In re Kerkhoven* is inapplicable to the present application because [it] was premised on a finding that ... obviousness is made out when you combine two compositions, each of which is taught by the prior art to be useful for the *same purpose* in order to form *a third composition that is to be used for the very same purpose*....

> This is not the situation in the present application. First, the composition taught in Weiler et al. contains three tannates one of which would have to be eliminated before the tannate disclosed in the Japanese reference could be added. Furthermore, the respective tannates have different pharmaceutical activities (e.g. antihistamine vs. antitussive). This is unlike ... *Kerkhoven* wherein the active ingredients have an identical function (i.e. detergents).

(*Id.* at 44-48.)

The examiner conducted a telephone interview with the applicant regarding the First Amended Application. The summary of that First Interview states that a list of co-pending or related cases was requested, and the applicant supplied five specified patent application numbers. (*Id.* at 53.)

The First Amended Application received a nonfinal rejection for obviousness in the Second Office Action. (*Id.* at 55-59.) However, in so holding, the examiner found persuasive all of the applicant's previous arguments distinguishing Weiler et al. and the Japanese reference. This time the examiner referred to a drug sold by Luchem in the United States under the trade name Histatuss ("the Luchem reference"), stating:

> The [Luchem] reference discloses a therapeutic composition ... having the antitussive carbetapentane tannate, the antihistamine chlorpheniramine tannate and the decongestants phenylephrine tannate and ephedrine tannate. The claims differ in the addition of one ingredient, ephedrine tannate. The present claims are directed to the antihistamine pyrilamine tannate. However, one skilled in the art would have been motivated to prepare a therapeutic composition comprising specific antihistamines or decongestants that exhibit a more favorable adverse effect profile.

> The skilled artisan in formulation chemistry through no more than routine experimentation would have been motivated to prepare a composition having a decongestant, anti-tussive agent and antihistamine ... for use in the treatment of cough associated with adverse respiratory tract conditions in view of the reference. Nothing unobvious is noted in the interchange of various agents within established categories of drugs.

(*Id.* at 57.)

> (3) Second Amended Application and Second Interview

The Second Amended Application modified claim 7 by inserting the words underlined below:

> A therapeutic composition for the symptomatic relief of cough associated with adverse respiratory tract conditions in warm-blooded animals in need of such treatment said composition comprising pharmaceutically effective amounts of *active ingredients, wherein said active ingredients consist of* carbetapentane tannate, pyrilamine tannate and phenylephrine tannate.

(*Id.* at 62, 65.)

The Second Amended Application was accompanied by a brief in which the applicant explained the latest amendment and argued against the obviousness rejection contained in the Second Office Action, stating as follows:

> To address the rejection ..., independent claim 7 has been amended so that its therapeutic composition is now comprising pharmaceutically effective amounts of "active ingredients, wherein said active ingredients consist of" carbetapentane tannate, pyrilamine tannate, and phenylephrine

tannate. The claim as directed to these active ingredients is believed to distinguish over the prior art reference....

....

The rejection distills the invention down to a "gist or thrust" thereby failing to consider the invention "as a whole." The novelty of the present invention, as a whole, is the active ingredient combination of the three specific tannates. The invention is not, as the rejection would suggest, the haphazard combining of an antihistamine, an antitussive, and a decongestant. The [Luchem] reference, as a whole, does not teach an antihistamine, an antitussive, and two decongestants. It teaches four specific tannates only two of which are common to the claimed invention. That the claimed invention eliminates one of the reference's decongestants, while retaining decongestant function, serves to illustrate the invention's nonobviousness....

...

Luchem contains no suggestion that would motivate one of ordinary skill in the art to make the needed modifications. Little more than a cryptic drug launch announcement for Hisatuss, ... Indeed, containing not a single sentence, Luchem does not speak at all. More importantly, the rejection does not explain how Luchem would suggest to one of ordinary skill ... that Luchem should be modified *both* to exclude Luchem's teachings of chlorpheniramine tannate and ephedrine tannate and to add the instant claims' teaching of pyrilamine tannate.

...

.... Insofar as Luchem contains no rhetoric whatsoever, it could hardly suggest its modification expressly.

.... That Luchem's meager disclosure of an ingredient list would *implicitly* suggest to one of ordinary skill in the cough-suppressant art that they should entirely eliminate one of Luchem's two decongestants and replace its antihistamine with a more than seven-fold measure of an entirely different antihistamine, seems doubtful at best.

.... Citing nothing in Luchem for either *express* or *implicit* motivation, the rejection offers that the artisan would have been motivated "through no more than routine experimentation." While this might be true, "[p]atentability shall not be negatived by the manner in which the invention was made." 35 U.S.C. § 103(a). And, whether a particular combination might be "obvious to try" is not a legitimate test of patentability....

.... It would appear to be the rejection's position then, that Luchem's teaching would render obvious *both* the *use* of *any* antihistamine and the *non-use* of *any* other decongestant in combination with carbetapentane tannate and phenylephrine tannate....

...

Luchem does not teach all of the limitations of the instant claims. The active ingredients" of claim 7, as herein amended -- and of the other claims amended or not, which depend directly or indirectly therefrom - - are limited to carbetapentane tannate, phenylephrine tannate, and pyrilamine tannate. By contrast, Luchem teaches the combination of carbetapentane tannate,

> phenylephrine tannate, chlorpheniramine tannate, and ephedrine tannate. To the extent that Luchem fails to teach the use [of] pyrilamine tannate, and to such further extent teaches the use of chlorpheniramine tannate and ephedrine tannate, it does not render *any* of the instant claims obvious.

(*Id.* at 66-71.)

The Second Amended Application was also submitted with a disclosure statement listing the following products, with their active ingredients and dosage amounts, as believed to be material to patentability:

Product Name	Listed Ingredients
Tussi-12 (orig.) suspension	carbetapentane tannate, chlorpheniramine tannate, phenylephrine tannate
Tussi-12(orig.) tablet	carbetapentane tannate, chlorpheniramine tannate, phenylephrine tannate
Rynatan(orig.) suspension	chlorpheniramine tannate, pyrilamine tannate, phenylephrine tannate
Rynatan(orig.) tablet	chlorpheniramine tannate, pyrilamine tannate, phenylephrine tannate
Ryna-12 S suspension	pyrilamine tannate, phenylephrine tannate
Ricotuss Sus suspension	carbetapentane tannate, chlorpheniramine tannate, phenylephrine tannate

Ricotuss Sus 10-8-60 suspension	carbetapentane tannate, chlorpheniramine tannate, phenylephrine tannate
Ricotuss Tab tablet	carbetapentane tannate, chlorpheniramine tannate, phenylephrine tannate

(*Id.* at 74-76.) A further submission with the Second Amended Application was an Information Disclosure Statement (Form PTO-1449), listing two patents issued to Gordziel (numbers 6,306,904 and 6,287,597) as relevant prior art. (*Id.* at 79-82; *see also* n.14 *infra* and accompanying text.)

The examiner conducted a telephone interview regarding the Second Amended Application on April 17, 2002. The summary of that Second Interview states that agreement was reached with respect to the claims, and describes the substance of that interview:

> [The applicant] documented the status and subject matter in various co-pending and related applications. They are set forth in the communication filed April 17, 2002 and attached hereto.

(P-35 at 90.) Attached to the Second Interview summary is a Supplemental Statement from the applicant (bearing fax and mailing notations as of April 17, 2002) containing the following information regarding prior PTO patents and/or applications (by applicant and others):

Filing Date	Listed Ingredients
11-30-00	carbetapentane tannate, chlorpheniramine tannate
3-14-00[14]	phenylephrine tannate, chlorpheniramine tannate
12-11-98	carbetapentane tannate, chlorpheniramine tannate, phenylephrine tannate
1-26-01	carbetapentane tannate
8-22-01	carbetapentane tannate, guaifenesin
8-22-01	phenylephrine tannate, guaifenesin

(*Id.* at 83-85.)

As stated, the Second Interview and submission of the applicant's Supplemental Statement both occurred on April 17, 2002. The Notice of Allowability of the Second Amended Application was issued on April 23, 2002.

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[14] This reference is to a Gordziel patent No. 6,037,358, issued on March 14, 2000. (P-35 at 84.) It is an additional tannate Gordziel patent to those previously identified in the Form PTO-1449 filed with the Second Amended Application. The Gordziel '358 patent is not identified in the '206 patent as a cited reference, although the other two Gordziel patents are so cited. (*See* P-2; *see also* P-35 at 9.)

II. DISCUSSION

A. Jurisdiction; Standard for Preliminary Injunction

MedPointe seeks preliminary injunctive relief for patent infringement. It alleges that both defendants have violated 35 U.S.C. § 271(a) (stating that "whoever without authorization makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent"). (Prasco Compl. ¶ 13; Hi-Tech Compl. ¶ 13.) The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The Court may grant injunctive relief under 35 U.S.C. § 283, which authorizes courts "to grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable."

A party must establish the right to a preliminary injunction based on four factors:

> (1) its reasonable likelihood of success on the merits; (2) irreparable harm to its interests; (3) the balance of hardships tipping in its favor; and (4) public interest in favor of the injunction.[15]

Glaxo Group Ltd. v. Ranbaxy Pharms., Inc., 262 F.3d 1333, 1335-36 (Fed. Cir. 2001). The Court "must balance these factors against one another and against the extent of the relief sought." *Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1219 (Fed. Cir. 1996); *see Hybritech Inc. v. Abbott*

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[15] The Court need not resolve the issue of whether the criteria for awarding a preliminary injunction are controlled by Federal Circuit or regional circuit case law since the Federal Circuit's standard is identical to that of the Third Circuit. *A.K. Stamping Co., Inc. v. Instrument Specialties Co.*, 106 F. Supp. 2d 627, 649 n.32 (D.N.J. 2000).

Labs., 849 F.2d 1446, 1451 (Fed. Cir. 1988). The movant bears the burden of proving entitlement to relief. *See Id.* Regardless of how the Court resolves the third and fourth factors, the movant must demonstrate the existence of the first two before the Court will grant a motion for a preliminary injunction. *Reebok Int'l v. J. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994).

The grant of a preliminary injunction is vested within the Court's sound discretion. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). "The standards applied to the grant of a preliminary injunction are no more nor less stringent in patent cases than in other areas of the law." *H.H. Robertson Co. v. U.S. Deck, Inc.*, 820 F.2d 384, 387 (Fed. Cir. 1987), *abrogated on other grounds by, Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (1995) (en banc), *aff'd*, 517 U.S. 370 (1996). A preliminary injunction is an extraordinary remedy. *See, e.g., Intel Corp. v: ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993). This special status, however, does not mean that it is unattainable. *See, e.g., Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 977 (Fed. Cir. 1991).

B. Likelihood of Success on the Merits

A patentee moving for a preliminary injunction has the burden of establishing its likelihood of success on the merits. *Boehringer Inqelheim Animal Health, Inc. v. Sherinq-Plough Corp.*, 984 F. Supp. 239, 247 (D.N.J. 1997). MedPointe must thus show that: (1) it will likely prove that the defendants infringe the '206 patent and (2) its infringement claim will likely withstand the defendants' challenges to the validity and enforceability of the '206 patent. *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997). If the defendants raise a "substantial question" concerning either infringement or validity, *i.e.*, a defense that MedPointe cannot prove "lacks substantial merit," the Court should not issue a preliminary injunction. *Amazon.com*, 239 F.3d at 1350-51; *see*

New England Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 883 (Fed. Cir. 1992).

MedPointe argues that a reasonable likelihood of success on the merits exists because Prasco's and Hi-Tech's proposed manufacture, use, and sale of C-Tanna 12D and Tannate-12DS infringe the '206 patent. (Pl. Pr. Br. at 6-8; Pl. Hi. Br. at 6-8; Reply to Prasco Br. at 8-21; Reply to Hi-Tech Br. at 8-16.) Both Prasco and Hi-Tech respond that they have raised substantial questions as to the invalidity of the '206 patent on obviousness grounds, and thus MedPointe cannot meet its burden. (Prasco Br. at 20-33; Hi-Tech Br at 7-21.) Hi-Tech also argues unenforceability because of MedPointe's inequitable conduct, (Hi-Tech Br. at 21-25), but has stipulated that its Tannate-12DS infringes the '206 patent, should the '206 patent be valid and enforceable. (12-22-03 Stip.) Prasco does not concede infringement, arguing that the presence of a previously-undisclosed fourth active ingredient puts its C-Tanna 12D beyond the scope of the '206 patent. (Prasco Br. at 5-20.)

The Court agrees with MedPointe and, for the reasons stated below, finds that it has satisfied the reasonable likelihood of success requirement.

(1) Construction of the '206 Patent

"It is elementary in patent law that, in determining whether a patent is valid and, if valid, infringed, the first step is to determine the meaning and scope of each claim in suit." *Lemelson v. Gen. Mills, Inc.*, 968 F.2d 1202, 1206 (Fed. Cir. 1992). "Only when a claim is properly understood can a determination be made whether the claim 'reads on' an accused device or method, or whether the prior art anticipates and/or renders obvious the claimed invention." *Amazon.com*, 239 F.3d at 1350. "Because the claims of a patent measure the invention at issue, the claims must be interpreted and given the same

meaning for purposes of both validity and infringement analyses." *Id.* (citation omitted).

The Court, in construing a patent claim, looks first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification, and the complete prosecution history. *Markman*, 52 F.3d at 979. While the written description may also aid in the proper construction of a claim term, any limitations, examples, or embodiments that appear only there may not be read into the claim. *Comark Comm., Inc. v. Harris Corp.*, 156 F.3d 1182, 1186-87 (Fed. Cir. 1998).

Intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). The Court, when examining intrinsic evidence, first "look[s] to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." *Id.* at 1582 (citation omitted). When doing so, the Court must bear in mind the heavy presumption that a claim term carries its ordinary and customary meaning unless the patentee has "clearly set forth a definition of the disputed claim term in either the specification or prosecution history." *CCS Fitness Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). Moreover, dictionaries, encyclopedias and treatises

> are always available to the court to aid in the task of determining meanings that would have been attributed by those of skill in the relevant art to any disputed terms used by the inventor in the claims. ... Thus, categorizing them as 'extrinsic evidence' or even a 'special form of extrinsic evidence' is misplaced and does not inform the analysis.

Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202-03 (Fed. Cir. 2002).

(a) Level of Ordinary Skill in the Art

Claims are interpreted "in light of the specification and with the knowledge of one of ordinary skill in the art." *Apex, Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1373 (Fed. Cir. 2003), *cert. denied*, __U.S. __, 2003 WL 22052036 (Dec. 8, 2003). We will now determine the level of ordinary skill for a practitioner in the art of pharmaceutical chemistry.

MedPointe's expert, Irving W. Wainer, Ph.D, asserted that a person of "ordinary skill in pharmaceutical chemistry would have had at least a B.S. degree, or its equivalent, in chemistry, pharmacology or pharmacy, and additional experience in the development and/or evaluation of drug products and therapies." (Wainer Decl. ¶ 13(A).) Hi-Tech' s expert, James O'Donnell, Pharm. D., attested to a comparable standard, i.e., a Bachelor's degree in pharmacy. (O'Donnell Testimony, 12-24-03 Tr. at 15.) Wainer noted that his interpretation of ordinary skill in the relevant art was the same as O'Donnell's. (Wainer Testimony, 12-22-03 Tr. at 78-79.)

The parties, in the main, agree on the applicable standard of one ordinarily skilled in the applicable art. The Court thus finds that one so skilled would have had at least a B.S. degree, or its equivalent, in chemistry, pharmacology or pharmacy, with some additional experience in the development or evaluation of drug products and therapies.

(b) Claim 1 Does Not Preclude the Presence of "Active Ingredients" in Less Than "Pharmaceutically Effective Amounts," Takinq the Dosage Period of the "Therapeutic Composition" into Account

A patent is infringed if any claim is infringed. *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1220 (Fed. Cir. 1995). Claim 1 is the only independent claim of the '206 patent. If there is no infringement of Claim 1, once properly-construed, there can be no infringement of the dependent claims. *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 799 (Fed.

Cir. 1990) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.") (quotation omitted).

We first look to the language of Claim 1, which states:

> 1. A therapeutic composition for the symptomatic relief of cough associated with adverse respiratory tract conditions in warm-blooded animals in need of such treatment said composition comprising pharmaceutically effective amounts of active ingredients, wherein said active ingredients consist of carbetapentane tannate, pyrilamine tannate and phenylephrine tannate.

(P-2, Col. 4.)

Prasco argues that the prosecution history of the '206 patent shows that Claim 1 was narrowed to "include only these three particular tannates, and cannot include any other active ingredients." (Prasco Br. at 13.) MedPointe, for the purposes of this motion, "does not dispute that Claim 1 of the '206 patent and its dependent claims cover only those products that contain pharmaceutically effective amounts of [the three actives]." (Reply to Prasco Br. at 9.) MedPointe does contend, however, that a proper construction of Claim 1 permits the presence of active ingredients in less than pharmaceutically effective amounts. (*Id.* at 9-11.) For the reasons set forth below, we agree with MedPointe.

> (i) Preamble of Claim 1 Constitutes a Claim Limitation That There be a "Therapeutic Composition for the Symptomatic Relief of Cough"

"[E]ach claim is an *entity* which must be considered *as a whole*." *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1274 (Fed. Cir. 1992). "A patent claim is normally divided into three sections: (1) the preamble; (2) the transition; and, (3) the body." *Bristol-Myers Squibb Co. v.*

Immunex Corp., 86 F. Supp. 2d 447, 450 (D.N.J. 2000). "The preamble is that portion of the claim preceding the [transitional phrase, such as] 'comprising.'" *Boehringer*, 984 F. Supp. at 247. Where the preamble is "necessary to give life, meaning and vitality to the claim" or is "essential to point out the invention defined by the claim," it effectively limits the scope of the claim. *Bell Commun. Research, Inc. v. Vitalink Commun. Corp.*, 55 F.3d 615, 620-21 (Fed. Cir. 1995). Conversely, "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation." *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997).

The preamble of Claim 1 sets forth the purpose or use of the claimed "therapeutic composition," *i.e.*, "the symptomatic relief of cough associated with adverse respiratory tract conditions in warm-blooded animals in need of such treatment." (P-2, Col. 4.) The preamble is more than-merely descriptive, however, because the body of Claim 1 is incomplete. We hold that the preamble gives meaning to the otherwise-empty phrase "pharmaceutically effective amounts of active ingredients, wherein said active ingredients consist of carbetapentane tannate, pyrilamine tannate and phenylephrine tannate."

We thus hold as our first construction that:

1) Claim 1 must be a "therapeutic composition" intended for the "symptomatic relief of cough" associated with "adverse respiratory tract conditions" in warm-blooded animals, *i.e.*, mammals and birds. (*See id.*, Col. 3-4.)

(ii) Because the Main Transitional Phrase of Claim 1 is the Open "Comprisinq," Claim 1 Does Not Preclude the Presence of "Active Inqredients" Not Part of the "Therapeutic Composition" in Less Than "Pharmaceutically Effective Amounts"

Prasco's claim construction argument hinges on the identity of the transitional phrase in Claim 1. The Manual of Patent Examining Procedure ("MPEP") states that "[t]he transitional phrases 'comprising', 'consisting essentially of' and 'consisting of' define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim." MPEP § 2111.03 (2001 ed.). "The transitional phrase 'consisting of' excludes any element, step, or ingredient not specified in the claim." *Id.* In contrast, "[t]he transitional term `comprising', which is synonymous with 'including,' 'containing,' or 'characterized by,' is inclusive or open-ended and does not exclude additional, unrecited elements or method steps." *Id.*

Prasco argues that the "consist of" within Claim 1 makes it a closed claim. (Prasco Br. at 9.) This term, however, follows an open transitional phrase, "comprising." (*See* P-2, Col. 4.) The MPEP states that "[w]hen the phrase 'consists of' appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element [sic] set forth in that clause; other elements are not excluded from the claim as a whole." MPEP § 2111.03 (citing *Mannesmann Demag Corp. v. Engr. Metal Prods. Co.*, 793 F.2d 1279 (Fed. Cir. 1986)). We cannot construe "consist of" as Claim 1's transitional phrase as that would render the preceding "comprising" a nullity. By that same token, however, "consist of" must have some limiting effect on the composition's "active ingredients" for the same reason.

We hold that the transition of Claim 1 is "comprising." The body of the claim is thus open but the dependent clause "active ingredients" is closed. We interpret this to mean that the "therapeutic composition" must include the three named active ingredients and they must be present in "pharmaceutically effective amounts." Claim 1, however, does not otherwise restrict the presence of "active ingredients" that are present in less than "pharmaceutically effective amounts."

Our interpretation is borne out by the '206 patent's File History. MedPointe added "consist of" while trying to surmount the PTO's second denial for obviousness. (*See supra*, Patent File History, § I.D.) MedPointe stressed to the PTO that "the specification conceives that the invention is the novel combination of only three active ingredients, specifically the tannates of carbetapentane, pyrilamine, and phenylephrine." (P-35 at 72.)

The Patent File History, however, does not preclude the presence of other "active ingredients" in less than pharmaceutically effective amounts." (*See supra*, Patent File History, § I.D.) Were we to construe Claim 1 as not permitting any non-"pharmaceutically effective amounts" of other substances within the composition, we would not be respecting the language that survived the patent examination process.

We thus further construe Claim 1 to require:

2) The "therapeutic composition" itself must contain three and only three "active ingredients" that are present in "pharmaceutically effective amounts": carbetapentane tannate, pyrilamine tannate, and phenylephrine tannate.

3) Claim 1 does not preclude the presence of additional "active ingredients" that are present in less than "pharmaceutically effective amounts" in the "therapeutic composition."

(iii) "Pharmaceutically Effective Amounts" Requires That an "Active Ingredient" be Effective Throughout the Course of the Therapeutic Composition's Applicable Dosage Period, as Defined by its Tannate Active Ingredients

The "therapeutic composition" must provide the "symptomatic relief of cough." (*See* supra, Claim Constr. 1.) The composition must contain "pharmaceutically effective amounts" of the three recited "active ingredients" to

accomplish this goal. (*See supra*, Claim Constr. 2.) The composition may have extra "active ingredients" in less than "pharmaceutically effective amounts." (*See supra*, Claim Constr. 3.) It may not, however, include such additional "active ingredients" in "pharmaceutically effective amounts." (*See, e.g., supra*, Claim Constr. 3.) The remaining claim construction issue is the precise scope and meaning of the term "pharmaceutically effective amounts." Although it is clear that the permissible "active ingredients" are the three tannates, it is unclear what "pharmaceutically effective amounts" means.

We look first to the intrinsic evidence in determining the the meaning of "pharmaceutically effective amounts." Claim 1 does not define it. (*See* P-2.) The phrase was not of issue during MedPointe's prosecution of the '206 patent. (*See* supra, Patent File History, § I.D; P-35.) Looking to applicable dictionaries, *Dorland's Illustrated Medical Dictionary* (29th ed. 2000) defines neither "pharmaceutically" nor "effective." "Pharmaceutical" is defined as "1. pertaining to pharmacy or to drugs. 2. a medicinal drug." *Id.* at 1366. "Effectiveness" is defined as "1. The ability to produce a specific result or to exert a specific measurable influence. 2. the ability of an intervention to produce the desired beneficial effect in actual use; cf. efficacy." *Id.* at 570. The cross-referenced "efficacy" is defined as:

> 1. the ability of an intervention to produce the desired beneficial effect in expert hands and under ideal circumstances. Cf. *effectiveness*. 2. in pharmacology, the ability of a drug to produce the desired therapeutic effect; it is independent of *potency*, which expresses the amount of the drug necessary to achieve the desired effect.

Id. at 570. The relevant definition for "potency" is:

> 2. the relationship between the therapeutic effect of a drug and the dose necessary to achieve that effect; a drug with a higher potency will require a

> smaller dose to produce a given effect. Clinically, potency has little use except as a means to compare the relative activities of pharmaceutic agents. Cf. *efficacy*.

Id. at 1446.

The active ingredients, to be "pharmaceutically effective," must thus "produce the desired therapeutic effect." *Id.* at 570. They must also be present in sufficient amounts as to be potent for their purpose, *i.e.*, that "dose necessary to achieve" the "symptomatic relief of cough." *Id.* at 1446. The term "amounts" falls within the phrase "pharmaceutically effective amounts" and is modified by "pharmaceutically effective." Such "amounts" must thus be sufficient to "produce the desired therapeutic effect." In short, such "amounts" must be "potent," comprising "the dose necessary to achieve" the desired therapeutic effect. Therefore, "pharmaceutically effective amounts" means that there is a sufficient dose of "active ingredients" to provide the desired therapeutic effect. The desired therapeutic effect is the symptomatic relief of cough.

The ordinary meaning of "symptomatic relief of cough" is clear: the "therapeutic composition" must help keep the person taking it from coughing. "Pharmaceutically effective amounts" remains ambiguous, however, because the "symptomatic relief of cough" carries with it a necessary, but here unclear, temporal component. Were the "therapeutic composition" to prevent only one cough or to last for just five minutes, it would not provide the "symptomatic relief of cough" that Claim 1 requires. The composition would also need enough time to enter the system of the person using it. While the following colloquy by O'Donnell is not offered as evidence for claim construction purposes, it does demonstrate that to be "pharmaceutically effective" the "active ingredients" must last for longer than the hypothetical single cough:

> Q. Okay. You look at Claim 1. Is there any time period required - minutes, seconds, hours,

days - any time period that you can see specified in Claim 1 for the combination to be effective?

A. No.

Q. No. There isn't, right?

A. Correct.

Q. Even I know that. Now - so, this combination could be put together and formulated to work for five minutes, correct?

A. No.

Q. In theory? No?

A. Not even in theory.

(O'Donnell Testimony, 12-24-03 Tr. at 66.) The composition of tannate "active ingredients," assuming that they have efficacy against cough, must thus be present at no less than the minimal "pharmaceutically effective amount" that offers some "symptomatic relief from cough" for the minimal, but not a *de minimis*, period of time. There must thus be some minimal dosage period that is associated with a "pharmaceutically effective amount" of the three tannate active ingredients.

We return to the intrinsic evidence. Claim 1 states no dosage period. (*See* P-2.) Moreover, the dosage period of the claimed composition was not an issue during the prosecution of the '206 patent. (*See supra*, Patent File History, § I.D; P-35.) The '206 patent's Specification helps somewhat. It asserts that the '206 patent's particular "novel combination" of listed tannates is desirable because it produces a composition having "antitussive, antihistaminic and sympathomimetic decongestant properties superior to the use of any one of the tannate compounds alone." (P-2, Col. 2.) The whole is claimed to be worth more than the sum of its parts for the symptomatic relief of cough. It is unclear, however, how such superior efficacy affects the composition's needed potency, i.e., what is a

"pharmaceutically effective amount" and how long such a dose might provide the "symptomatic relief of cough."

The Examples in the Specification offer recommended doses for each tannate "active ingredient." (P-2, Cols. 2-3.) Example 1 is for tablets and suggests the following "preferabl[e]" doses: 60 mg of carbetapentane tannate; 10 mg of phenylephrine tannate; and, 40 mg of pyrilamine tannate. (*Id.*) Example 2 involves suspensions and suggests these "preferabl[e]" doses per 5 ml of suspension: 30 mg of carbetapentane tannate; 30 mg of pyrilamine tannate; and, 5 mg of phenylephrine tannate. (*Id.*) Neither Example explicitly states a dosing period that would be "pharmaceutically effective." The listed doses, however, presumably have dosing periods associated with them. Thus, the Examples further support our understanding that "pharmaceutically effective" must have some temporal component.

The Specification also states: "Antitussives, antihistamines and decongestants in the form of their tannate salts are very desirable because such salts are generally stable and may be combined in such form without any untoward side effects." (P-2, Cols. 1-2.) The Specification gives no further definition of the term "stable" nor explains why this quality is one that makes a composition of tannates medically desirable or "pharmaceutically effective." *Dorland's* defines "stable" in its ordinary sense: "not moving, fixed, firm; resistant to change." *Id.* at 1688. "Stability" is defined as "the quality of maintaining a constant character in the presence of forces which threaten to disturb it; resistance to change." *Id.*

"Stability" thus implies that the tannates recited in Claim 1 are relatively chemically inert; they should degrade little over time and in the face of adverse conditions. Again, there is no indication as to how long the tannates will last; "stable" is here only qualitatively descriptive, not quantitatively. But again, here is further support for our understanding that

"pharmaceutically effective" must have a temporal element to its definition.

We thus look, having failed to resolve this ambiguity from the intrinsic evidence alone, to the extrinsic evidence to that extent permissible, *i.e.*, "only to the extent that such evidence does not contradict the specification and file history." *Boehringer*, 984 F. Supp. at 246. We use expert testimony for enlightenment about the patent and the relevant technology. *Mantech Envtl. Corp. v. Hudson Envtl. Servs., Inc.*, 152 F.3d 1368, 1373 (Fed. Cir. 1998). We specifically look to expert witness testimony in order to shed light on the qualities of tannates, how these qualities help make them "pharmaceutically effective" and the relationship between the term "pharmaceutically effective amounts" and the dosage period of the three tannates.

D'Addio noted that the "therapeutic effect" of a tannate is not provided by its tannic acid component, but by its pharmaceutical base, *i.e.*, the carbetapentane, etc. (D'Addio Testimony, 12-23-03 Tr. at 66; *see also* Repoza Testimony, 12-22-03 Tr. at 215-16.) This "therapeutic effect" is the same regardless of the salt to which the base is bound. (*See* D'Addio Testimony, 12-23-03 Tr. at 66.) Only the pharmaceutically active base, and not the salt, crosses the stomach lining into the bloodstream, the salt being merely the carrier. (O'Donnell Testimony, 12-24-03 Tr. at 53-54; Thomas Testimony, 12-23-03 Tr. at 109.) For example, phenylephrine hydrochloride and phenylephrine tannate have the same pharmacological effect - as a decongestant - despite being different salts. The benefit of using the tannate form of a drug, as opposed to another salt containing the same pharmacologically-active base, must thus have to do with how a tannate performs its function as a carrier in contrast to other salts.

D'Addio testified that the Specification's description of tannate salts as "stable" reflected the applicable "historical knowledge" concerning them. (D'Addio Testimony, 12-23-03

Tr. at 67-68.) Stability sets tannates apart from other salts because the tannate salt form of a drug lasts longer than when it is bound to other salts. (*Id.* at 66-67.) "Stability" means that tannates are slowly absorbed and thus have an extended dosage period. (*Id.* at 82-83.) This quality of tannates can be beneficial and medically desirable; longer dosage periods assist physicians with patient compliance, for example, as one need not take as many doses of a tannate-based drug as that composed from different salts. (*See* O'Donnell Testimony, 12-24-03 at 57-59; D'Addio Testimony, 12-23-03 Tr. at 82-83.)

The "stability" of tannates thus helps us understand the temporal element of their "pharmaceutical effectiveness." Exchanging non-tannates for tannates of the same pharmaceutical bases within a composition changes the dosage period for the drug, shortening it by removing the extended-release benefit that the tannates allow. (O'Donnell Testimony, 12-24-03 Tr. at 57-58.) D'Addio testified that there was a "tremendous difference" between the "standard [non-tannate] salt form[]" of a drug and its tannate counterpart because the former "are intended for immediate [pharmacological] release and typically four to six hour dosing." (D'Addio Testimony, 12-23-03 Tr. at 82.)

D'Addio did not state the typical dosing period for the "pharmaceutically effective" tannate form of a drug. If the quality of tannates as "long acting...dosing products," (*see id.* at 83), were to have any meaning, however, it would have to be noticeably more than four to six hours. O'Donnell applied a benchmark dosage period of about twelve hours for a tannate-based composition:

> Q. And if [the ordinarily skilled practitioner] wanted to make a [pharmaceutical composition with an antitussive, antihistamine and a decongestant] last for 12 hours, what would one do?

> A. He [or she] would formulate it in a fashion that delays the release of the active ingredient prior to absorption across the gut membrane which takes it into the blood - try to slow down the absorption of the active ingredients.
>
> Q. And would one use a particular type of substance for that?
>
> A. Yes, it - the history of cough and cold is to use a tannate - a tannate salt in contrast to other salts.

(O'Donnell Testimony, 12-24-03 Tr. at 18.) O'Donnell further testified that if the ordinarily skilled practitioner wished to slow the "release of the [free base] active ingredients for 12 hours" in a drug with the same active bases as those in Claim 1, but composed of different salt forms, he or she would replace the respective salts with their tannate counterparts. (*Id.* at 32.)

Medpointe's product is itself helpful in interpreting the temporal component of "pharmaceutically effective amounts." Tussi-12D is MedPointe's preferred embodiment of the '206 patent. Tussi-12D's package insert gives the following doses: per tablet, 60 mg carbetapentane tannate, 10 mg phenylephrine tannate, 40 mg pyrilamine tannate; for a suspension, per 5 ml, 30 mg carbetapentane tannate, 5 mg phenylephrine tannate, 30 mg pyrilamine tannate. (P-48.) These are the same dose amounts as the "preferabl[e]" doses recited in the Examples within the `206 patent's Specification. (P-2, Cols. 2, 3.) Testimony as to the dosage period for the Tussi-12D embodiment should thus inform us as to the resulting and "preferabl[e]" dosage period associated with the "preferabl[e]" doses recited by the patent itself.

Wainer estimated that, when administered according to its instructions, the "dosing period" for Tussi-12D is twelve hours. (Wainer Testimony, 12-22-03 Tr. at 102.) Prasco's C-Tanna 12D and Hi-Tech's Tannate-12DS both recite the same

components, in the same amounts, as Tussi-12D and the Specification's Examples. (*See* P-3; P-6; Seltzer Tr. at 17, 41-43.) Wainer testified that the dosing period for each accused product was thus twelve hours as well. (Wainer Testimony, 12-22-03 Tr. at 102.)

We find that the specific temporal quality arising from the stability of tannates is that they have a longer dosage period than comparable salts. However, though the dosage period associated with the preferred "pharmaceutically effective amounts" of the "active ingredients" recited in Claim 1 is twelve hours, Claim 1 is not necessarily limited to this dosing period. We find only that the Claim 1 composition must provide the "symptomatic relief of cough" over an extended period of time compared with compositions of other salts. We suggest, based upon the expert testimony, that a tannate-based composition would last for approximately two to three times as long as comparable "pharmaceutically effective amounts" of the same drug carried by a different salt form. (*See* D'Addio Testimony 12-23-03 Tr. at 82; Wainer Testimony, 12-22-03 Tr. at 102.)

Our giving temporal scope to Claim 1 does not contradict the patent itself or its File History. The '206 patent does not, as noted, recite a dosage period itself. (P-2; *see* Wainer Testimony, 12-22-03 Tr. at 116.) The patent examiner was concerned with the obviousness of the composition; she never addressed the issue of its dosing period or even dosage forms, outside of noting that the "[f]ormulation of various dosage forms is conventional."[16] (P-35 at 57.)

We thus finally address the temporal aspect of what is permissible in additional "active ingredients." We find that an "active ingredient" is only present in Claim 1's therapeutic

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[16] Moreover, the patent examiner never addressed whether the composition could not have additional substances in less than "pharmaceutically effective amounts." (*See supra*, Patent File History, § I.D; P-35 at 32-33, 56-57.)

composition in "pharmaceutically effective amounts" if it has both efficacy and potency comparable to the composition's recited tannates. Claim 1 thus excludes "active ingredients" that provide the "symptomatic relief of cough" for the same dosing period as that of the tannates.

Our interpretation is borne out by the permissible expert witness testimony. Wainer noted that active ingredients present in less than "pharmaceutically effective amounts" can still have a pharmacological effect on the one ingesting a composition with them. (Wainer Testimony, 12-22-03 Tr. at 97-100.) The ordinarily skilled practitioner would thus construe this phrase in light of the goal set for the composition of "active ingredients." (*Id.* at 82, 99.) "Pharmaceutically effective amounts" of "active ingredients" must assist in the "symptomatic relief of cough" throughout the entirety of their normal dosage period. (*Id.* at 82-85, 97-100; *see* Rapoza Testimony, 12-22-03 Tr. at 240-41.)

Wainer testified that a substance that would be metabolized long before the tannate "active ingredients" were cannot be considered "pharmaceutically effective," at least in Claim 1's relative sense. (Wainer Testimony, 12-22-03 Tr. at 101-04; *see* P-126; P-228.) Wainer cited phenylephrine hydrochloride as an example. (Wainer Testimony, 12-22-03 Tr. at 101-04.) It has a dosage period of four hours. (*Id.* at 101.) The dosage period of Tussi-12D is twelve hours. (*See id.* at 102.) Phenylephrine hydrochloride absorbed with Tussi-12D could have its own pharmacological effect. (*See id.*) It would, however, be metabolized long before the tannates in Tussi-12D had run their course; that is, the phenylephrine hydrochloride would have fallen to a less than "pharmaceutically effective level" hours earlier. (*Id.* at 103-04.)

We thus finally construe Claim 1 to require:

4) "Pharmaceutically effective amounts" means: present in sufficient quantities to provide the "symptomatic relief of cough" for at least as long as the dosage period associated with the three recited tannates.

Therefore, an "active ingredient" is not present in "pharmaceutically effective amounts" if it does not provide the "symptomatic relief of cough" for at least as long as the dosage period resulting from administering the three recited tannates.

(2) The Defendants Raise No "Substantial Question" as to the Validity of the '206 Patent

The next issue is whether the defendants have raised a "substantial question" as to Claim 1's obviousness, now that we have construed it. *Lemelson*, 968 F.2d at 1206. MedPointe does not need to prove the validity of the '206 patent: in light of the presumption of validity, that burden always rests with the patent challenger. *Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1998) ("[A] patent is presumed valid, and this presumption exists at every stage of the litigation."). The alleged infringers must at least identify some persuasive evidence of invalidity at the preliminary injunction stage to overcome the presumption of validity. *Id.* ("Where the challenger fails to identify any persuasive evidence of invalidity, the very existence of the patent satisfies the patentee's burden on the validity issue.").

(a) The Defendants Have Not Raised a "Substantial Question" Regarding the Obviousness of Claim 1

A patent claim is invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a). "The ultimate legal conclusion of obviousness is a question of law." *Miles Labs., Inc. v. Shandon Inc.*, 997 F.2d 870, 877 (Fed. Cir. 1993). Our obviousness analysis, however, is based on our findings of fact involving:

> (1) the scope and content of the prior art; (2) the differences between the prior art devices and the claimed invention; (3) the level of ordinary skill in the art; and (4) any other objective evidence. of nonobviousness.

Tyco Indus., Inc. v. Tiny Love, Ltd., 914 F. Supp. 1068, 1079-80 (D.N.J. 1996) (citations omitted). These four factual inquiries are called the *Graham* factors. *See McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1349 (Fed. Cir. 2001) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). The Court's findings of fact for these factors are numbered 1-15 in the Discussion that follows. (*See infra.*)

The ultimate legal issue is whether the recited composition in Claim 1 would have been obvious to a practitioner of ordinary skill, thereby rendering the `206 patent invalid. The defendants argue that Claim 1 is an obvious re-combination of well-known and interchangeable components. (Prasco Br. 20-33; Hi-Tech Br. at 8-21.) They argue that an ordinarily skilled practitioner could have hit upon the Claim 1 composition through a number of routes and would have discerned a suggestion or motive within the prior art to do so. (*Id.*) MedPointe primarily replies that the PTO's decision to grant the '206 patent despite having been informed of the relevant prior art should receive due deference, especially in light of the favorable "secondary indicia" of non-obviousness. (Reply to Prasco Br. at 16-21; Reply to Hi-Tech Br. at 9-15.)

(i) Level of Ordinary Skill in the Art

1) The Court restates the previous finding, i.e., that one so skilled would have had at least a B.S. degree, or its equivalent, in chemistry, pharmacology or pharmacy, with some additional experience in the development or evaluation of drug products and therapies. (*See supra*, § II.B.(1)(a).)

(ii) Scope and Content of the Applicable Prior Art

"Determining whether there is a suggestion or motivation to modify a prior art reference is one aspect of determining the scope and content of the prior art, a fact question subsidiary to the ultimate conclusion of obviousness." *Tec Air, Inc. v. Denso Mfg.*, 192 F.3d 1353, 1359 (Fed. Cir. 1999). Thus, the ultimate factual issue is whether the prior art would have given an ordinarily skilled practitioner some motivation to re-combine these three particular actives, and in their tannate salt forms. We will address this question in the following sub-sections.

The Court first makes these findings:

2) Each of the three pharmaceutical components detailed in Claim 1 has been well-known since before 1962 to ordinarily skilled practitioners for its respective purpose, *i.e.*, carbetapentane as an anti-tussive, phenylephrine as a decongestant and pyrilamine as an antihistamine. (O'Donnell Testimony, 12-24-03 Tr. at 16-18; *see* PR-10; PR-18; D-14; D-15.)

3) Tannates generally are well-known to ordinarily skilled practitioners, and each of the three listed pharmaceuticals has long been known in its tannate salt form. (O'Donnell Testimony, 12-24-03 Tr. at 16-20; *see* D-13.)

4) Tannates are known to be relatively insoluble, and thus an ordinarily skilled practitioner would know that tannate salts of pharmaceuticals are longer-lasting, *i.e.*, have a longer dosage period. (O'Donnell Testimony, 12-24-03 Tr. at 18, 32-33, 58-59; D'Addio Testimony, 12-23-03 Tr. at 82-83.)

5) There have been many drugs produced over the years that incorporate and combine these three pharmaceutical components, including the tannate salt forms of each. (O'Donnell Testimony, 12-24-03 Tr. at 16-33; *see* D-13; D-14; D-15.)

6) A number of these latter tannate-based compositions were or are produced by MedPointe or its predecessor, Carter-Wallace. (PR-1; D-7; D-8; D-10.)

7) MedPointe cited many of these products as material in '206 patent application in a disclosure statement submitted with its Second Amended Application in March 2002. (*Compare* D-7; D-8; D-10 *with* P-35 at 74-76.)

8) MedPointe also submitted a supplemental disclosure statement setting forth the two "Gordziel" patents as relevant prior art. (P-35 at 79-82; *see* PR-24.)

9) MedPointe thereafter submitted, in response to a telephone request from the Patent Examiner, another supplemental disclosure statement describing the composition claims of another patent and five other then-recent pending or abandoned patent applications. (P-35 at 83-85.)

10) This composition of three tannate salts had not been produced before the filing date of the '206 patent, January 26, 2001. (O'Donnell Testimony, 12-24-03 Tr. at 23, 43, 59.)

(a) Summary of Defendants' Obviousness Arguments in Light of Ultimate Factual Issue as to Whether There Was a Suggestion or Motive to Re-Combine References in the Prior Art

The defendants argue that Claim 1 represents an obvious and simple re-combination of prior art references. First, they argue that Claim 1 is rendered obvious by the otherwise-identical compositions of two of MedPointe's prior products, Tussi-12 and Ricotuss, both of which included chlorpheniramine as an antihistamine, because the antihistamines chlorpheniramine and pyrilamine are interchangeable. (Prasco Br. at 20-32; Hi-Tech Br. at 12-15.) Second, they argue that Claim 1 is obvious in light of the prior existence of MedPointe's Ryna-12S, which was composed of pyrilamine tannate and the decongestant phenylephrine tannate, because it would have been obvious to add an antitussive such as carbetapentane tannate to a tannate-based cough/cold remedy lacking one. (Prasco Br. at 32-33; Hi-Tech Br. at 16-17.) Third, it is argued that, when combined, the

Tussi-12 and Ryna-12S references render Claim 1 obvious, as do various other modifications of the prior art, such as that of "Candettes," an old composition containing all three of the `206 patent's listed pharmaceutical bases, but in different salt forms. (*Id.* at 15-19.)

The Court is not persuaded by the defendants' evidence that the prior art suggested the re-combination or interchangeability of known pharmaceuticals to produce the composition in the '206 patent. MedPointe has shown that the factual core of the defendants' obviousness defense lacks "substantial merit." The defendants have thus failed to raise a "substantial question" of invalidity for obviousness. The basis for the Court's findings are articulated below.

(b) Chlorpheniramine and pyrilamine are not Interchangeable

MedPointe argues that chlorpheniramine and pyrilamine are not interchangeable. (Reply to Prasco Br. at 18-19; Reply to Hi-Tech Br. at 11-12.) We agree.

Prasco introduced evidence attesting that the two antihistamines are interchangeable. For example, the article "Antihistamines: An Overview of Past, Present, and Future" states that the "six classes of antihistamines ... are more or less equivalent in efficacy." (PR-10 at 1-2; *see* D-14 at 144-46.) Hi-Tech's expert witness, Dr. James O'Donnell, agreed that the two antihistamines are "therapeutically equivalent" drugs. (O'Donnell Testimony, 12-24-03 Tr. at 23.) He testified that these drugs, under various names, have been used for years and their standard dosages are well-known.[17] (*Id.* at 20-29; *see* D-13.) He thus opined that it would have been obvious to an ordinarily skilled practitioner to replace the 4 mg/5 ml and 5

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[17] Pyrilamine is also called "mepyramine" and carbetapentane tannate is also known as "pentoxyverine tannate." (O'Donnell Testimony, 12-24-03 Tr. at 20, 30; *see* D-13.)

mg of chlorpheniramine tannate respectively found in Tussi-12 suspension and tablets with the commensurate 30 mg/5 ml and 40 mg of pyrilamine tannate in Tussi-12D. (O'Donnell Testimony, 12-24-03 Tr. at 20-29; *see* D-13.)

MedPointe introduced evidence that the antihistamines are not equivalent. Wainer stated that the two pharmaceuticals are not interchangeable: chlorpheniramine is medically distinct from pyrilamine. (Wainer Decl. 9[9[71-74.) For example, the former is more of a stimulant and 10% of people have trouble metabolizing it. (*Id.* at 72.)

Dr. Harry J. Sacks, M.D., a MedPointe rebuttal expert, agreed with Wainer that chlorpheniramine and pyrilamine are not interchangeable. (Sacks Testimony, 12-24-03 Tr. at 84-94.) He stated that there is no one cough/cold formula for all patients, and would be concerned about the varying side effects of chlorpheniramine and pyrilamine, preferring one to the other depending on the patient. (*Id.*; *see* P-229.) He concluded that one cannot simply substitute one of these antihistamines for the other. (Sacks Testimony, 12-24-03 Tr. at 84-94.)

MedPointe's evidence is more persuasive. In fact, the article cited by Prasco states that the six classes of antihistamines "are more or less equivalent in efficacy but dissimilar in their side effects. These side effects help to further differentiate them and their clinical indications." (PR-10 at 1.) Likewise, Prasco witness Rapoza testified that, despite a common chemical "amine" backbone, chlorpheniramine is structurally "totally different" from pyrilamine. (Rapoza Testimony, 12-22-03 Tr. at 208-09.) He noted that the two drugs affect patients differently, especially in their sedative effect, despite having similar efficacy. (Rapoza Testimony, 12-22-03 Tr. at 210-11.) O'Donnell also noted that the different side effects of chlorpheniramine and pyrilamine, but thought such differences minor, holding to his opinion that the two drugs were "therapeutically equivalent." (O'Donnell Testimony, 12-24-03 Tr. at 22, 73-76)

11) We find that pyrilamine and chlorpheniramine are not interchangeable. Thus, the use of the former in a claim otherwise compositionally similar to a predecessor product containing the latter, *i.e.*, Tussi-12, would not have been obvious for this fact alone.

(c) The Defendants' Various Cited Factual References Would Have Only Rendered Claim 1 "Obvious to Try," at Most, to an Ordinarily Skilled Practitioner

Prasco's main obviousness argument is broader than the prior discussion implies. Prasco essentially contends that, in light of the prior art, MedPointe's "[s]imply substituting one well-known first generation antihistamine for another well-known first generation antihistamine is not patentable." (Prasco Br. at 30.) Hi-Tech likewise argues that the obviousness of the composition is clear because an ordinarily skilled practitioner could have arrived at it by combining a variety of references, the most telling being two specific to MedPointe, Tussi-12 and Ryna-12S. (Hi-Tech Br. at 15-19.) O'Donnell testified in support of both of these points. (O'Donnell Testimony, 12-24-03 Tr. at 19-31, 60-62, 75-80.)

The composition claim set forth in Claim 1 of the '206 patent seems simple. Simplicity, however, especially that construed after the fact, is not the test for obviousness. "While one could argue that in hindsight it may seem obvious to combine the [reference products and patents], the examination should not occur in hindsight." *Fuji Photo Film Co., Ltd. v. Jazz Photo Corp., Inc.*, 173 F. Supp. 2d 268, 275 (D.N.J. 2001). "The genius of invention is often a combination of known elements which in hindsight seems preordained." *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1371 (Fed. Cir. 2000). "When the art in question is relatively simple, as is the case here, the opportunity to judge by hindsight is particularly tempting. Consequently, the tests of whether to combine references need to be applied rigorously." *McGinley*, 262 F.3d at 1351.

An invention that is merely "obvious to try" is patentable. *See In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995). Prior art makes an invention "obvious to try" when a "general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure." *Gillette Co. v. S.C. Johnson & Son*, 919 F.2d 720, 725 (Fed. Cir. 1990). Moreover, the "prior art gives either no indication of which parameters are critical or no direction as to which of many possible choices is likely to be successful." *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989). "Teachings of references [may] be combined" to establish obviousness, but there must be some teaching, suggestion or incentive supporting the combination. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). Finally, the Court must consider the results achieved by the claimed combination. *Gillette*, 919 F.2d at 724.

The defendants cite two cases in which the alleged infringer had demonstrated the required clear and convincing evidence of a suggestion or motive to modify or re-combine the components of a pharmaceutical composition in the prior art. In *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362 (Fed. Cir. 2003), the Federal Circuit affirmed a bench trial verdict of obviousness where the plaintiff had patented the combination of its anti-diarrheal-medication with an anti-gas drug, simethicone. *See id.* at 1365-67, 1369-71. The district court had found that "the concurrence of diarrhea and flatulence had been noted in more than twenty prior art articles and publications." *McNeil-PPC*, 337 F.3d at 1369. It had noted that "combinations of several other well-known antidiarrheals with simethicone had been described in the prior art, even if they had not been commercialized." *Id.* at 1369-70. The Federal Circuit saw no error in the district court's finding that "all of the limitations in the asserted claims...were known and that there was motivation to combine those elements as of [the] asserted invention date." *Id.* at 1370.

In *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476 (Fed. Cir. 1997), the Federal Circuit affirmed a judgment as a matter of law in favor of the alleged infringer, which had reversed a jury verdict of nonobviousness in the patentee's favor. *See id.* at 1480-84. The plaintiff had patented the combination of the analgesic ibuprofen with a decongestant, pseudoephedrine. *See id.* The district court had noted that combining an analgesic with a decongestant was already known within the prior art as being effective at treating sinus headaches. *Id.* at 1483. Moreover, doctors had testified that they had been prescribing the combination of ibuprofen with pseudoephedrine together before the plaintiff patented its combination of both drugs in one pill. *Id.* at 1483-84. Finally, a year before the plaintiff filed its application, "numerous prior art publications announced that the [FDA] would approve ibuprofen as an over-the-counter medicine." *Id.* at 1484. The district court found that such evidence had "created a strong motivation to combine the two ingredients into a single unit dosage." *Id.*

The factual references cited by the defendants do not collectively present nearly so strong a suggestion or motive to re-combine as existed in *McNeil-PPC* or *Richardson*.[18] The defendants show that combinations of the three tannates and related drugs existed such that Claim 1 *could* have been replicated by re-combining the prior art in multiple ways. The defendants argue that the prior art would have presented a motive or suggestion to an ordinarily skilled practitioner, working from a variety of references, to exchange the chlorpheniramine tannate in Tussi-12 with pyrilamine tannate. (*See* Prasco Br. at 25-28; Hi-Tech Br. at 14-17.) The specific desirability, however, of replacing chlorpheniramine tannate

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[18] Both cases are procedurally distinguishable as well, as each involved a complete trial record. We note that our holding does not preclude the defendants from meeting their burden at trial of showing obviousness through the necessary clear and convincing evidence. *Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1364 (Fed. Cir. 1998)

with pyrilamine tannate in Tussi-12 had not been explicitly suggested by the prior art, unlike the various references suggesting the re-combinations at issue in *McNeil-PPC* and *Richardson*. A possibly restricted range of tannate pharmaceuticals from which the ordinarily skilled practitioner would have been able to choose, (*see* O'Donnell Testimony, 12-24-03 Tr. at 16-18), does not necessarily mean that the prior art directed that the Claim 1 composition would have been desirable or successful. *See Merck*, 874 F.2d at 807. This pathway to the `206 patent might have been quite "obvious to try," but it was not obvious.

The defendants alternatively argue that an ordinarily skilled practitioner would have found a suggestion or motive in the prior art to add carbetapentane to MedPointe's Ryna-12S, which lacked an anti-tussive. (Prasco Br. at 32-33; Hi-Tech Br. at 16-17.) To this end, O'Donnell testified that carbetapentane tannate was, by far, the most common of the tannate anti-tussive drugs; a practitioner would thus have found it obvious to add it to a slow-acting tannate-based composition lacking such an antitussive. (O'Donnell Testimony, 12-24-03 Tr. at 29-31, 78-79.)

The Court notes, of the scenarios cited by the defendants on the alleged obviousness of Claim 1, the Ryna-12S reference is the most compelling. *McNeil-PPC* and *Richardson* would appear to be readily applicable to this factual instance, with the prior art providing the suggestion or motive to render Ryna-12S effective against cough as well as cold, and for as long a dosage period. The record persuades us, however, that no specific motive or suggestion to re-combine pharmaceuticals existed in the prior -art, even as to Ryna-12S.

The evidence that tannates are difficult to work with is especially probative as to whether the prior art had presented a discernable motive or suggestion to re-combine existing tannate-based drugs. D'Addio, one of the inventors of the '206 patent, testified that tannates were hard to work with and that

he and his co-inventor Leflein experienced problems in formulating the '206 composition. (D'Addio Testimony, 12-23-03 Tr. at 19-23; *see* P-88; P-92.) Repoza agreed that tannates were generally hard to work with, "especially with liquids, because of their size." (Repoza Testimony, 12-22-03 Tr. at 246.) So did O'Donnell. (O'Donnell Testimony, 12-24-03 Tr. at 45-46.) Only Dondeti testified that he had no difficulties in working with them, whether generally or while trying to create a generic version of the Tussi-12D suspension. (Dondeti Testimony, 12-23-03 Tr. at 273-77.)

The Court is more persuaded by MedPointe's account. First, there is a minor consensus among the witnesses that tannates are difficult to work with. Dondeti's contrary report would seem to be less indicative, given his expertise, than D'Addio's, who had worked with the more "ordinarily skilled" B.S.-educated Leflein. (D'Addio Testimony, 12-23-03 Tr. at 21.) In this instance, "ordinary skill" would not require D'Addio's or Dondeti's experience. (*See* supra, § II.B.(2) (a) (i)). Second, the Hi-Tech witnesses had the benefit of working from hindsight: Dondeti worked with a known "reference product," Tussi-12D. (Dondeti Testimony, 12-23-03 Tr. at 271, 284-85.) O'Donnell's expert analysis *began* with his review of the '206 patent, which he had thought obvious on reading. (O'Donnell Testimony, 12-24-03 Tr. at 42-43, 63.) We are confident that these latter witnesses are sincere. However, we take seriously our duty to rigorously screen out hindsight, *see, e.g.*, *McGinley*, 262 F.3d at 1351, and thus are equally confident in siding with MedPointe on this factual issue.

12) The Court finds that it is difficult for practitioners of ordinary skill to work with tannates. The Court further finds that such a practitioner would thus not have been inclined to experiment with them barring an external reason for doing so.[19]

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[19] D'Addio, for example, only began his research after receiving a memo to proceed with his supposed idea for changing Tussi-12. (D'Addio Testimony, 12-23-03 Tr. at 13-18; see D-7.) Once he created the `206

13) The Court thus finds that the prior art would not have provided a motive or suggestion to a practitioner of ordinary skill to re-combine the existing pharmaceutical references so as to produce, and render obvious, the composition in Claim 1 of the '206 patent. These references would have, at most, rendered the composition "obvious to try."

(d) The PTO Addressed the Combination and Suggestion/Motive to Re-Combine Issues

MedPointe argues that the PTO's decision to grant it the '206 patent deserves deference. (Reply to Prasco Br. at 17; Reply to Hi-Tech Br. at 9.) We agree. This argument convinces us that the defendants have not raised a "substantial question" as to obviousness and further bolsters our finding that the prior art would have provided no suggestion or motive to an ordinarily skilled practitioner to re-combine existing. cough and cold compositions. (*See* supra, § II.B.(2)(a)(ii.c).)

"Where the PTO has considered a piece of prior art, and issued a patent notwithstanding that prior art, a court owes some deference to the PTO's decision." *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1572 (Fed. Cir. 1992) (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984)). "When a party alleges that a claim is invalid based on the very same references that were before the examiner when the claim was allowed, that party assumes [an] additional burden." *Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co.*, 204 F.3d 1360, 1367 (Fed. Cir. 2000). Specifically, the challenging party has the burden of:

> overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners

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composition, others copied it. Such copying, however, is more properly dealt with as a Graham "secondary consideration." *See infra*, § II.B.(2)(a)(iv)

> who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.

Am. Hoist, 725 F.2d at 1359.

The Court is convinced by its review of the '206 patent's Prosecution File History that both PTO and patent examiner properly did their jobs. MedPointe's original six claims were rejected by the PTO as obvious under 35 U.S.C. § 103(a) over a medical study involving MedPointe's Rynatan and a Japanese patent for carbetapentane. (*See* P-35 at 32-36.) The PTO again rejected MedPointe's re-drafted claims for obviousness over "Histatuss," a drug released by Luchem in 1991. (*See id.* at 56-59.)

The PTO thus addressed obviousness. The Histatuss exchange shows that the PTO made the broadest argument now brought by the defendants, *i.e.*, that the '206 composition could have been discovered. through "routine experimentation." (*See id.* at 57.) Moreover, the patent examiner had discerned a motive that acknowledges the differences between chlorpheniramine and pyrilamine, *i.e.*, to "prepare a therapeutic composition comprising specific antihistamines or decongestants that exhibit a more favorable adverse effect profile." (*Id.*)

MedPointe replied to the patent examiner, *inter alia*, that the Luchem reference presented no motive-to re-combine and that the examiner had applied an erroneous "obvious to try" standard. (*Id.* at 62-73.) MedPointe also supplemented its Second Amended Application with a 37 C.F.R. § 1.56(a) submission. describing the composition of eight MedPointe drugs. (*See supra*, Patent File History, § I.D.) All eight were comprised of varying doses and combinations of four tannates: the three listed in Claim 1 and chlorpheniramine tannate. (P-35 at 74-76.)

The examiner had before her at this point numerous pertinent material references with which to support the "invalid for obviousness" reasoning in the Second Office Action. (*See supra*, Patent File History, § I.D.) One such reference was to Ryna-12. (*See* P-35 at 75; *see also* O'Donnell Testimony, 12-24-03 Tr. at 80.) Another was to Gordziel patent No. 6,287,597 ("the '597 patent"). (*See* P-35 at 82.) The examiner thus had before her the particular references she needed to support a finding that there existed some suggestion or motive in the prior art to create the '206 composition.

These are the same references which the defendants now argue show Claim 1's obviousness. For example, Hi-Tech argues that the prior art would have showed a suggestion or motive to expand the capabilities of Ryna-12 by adding an anti-tussive. (Hi-Tech Br. at 16-17.) The same could be said of the '597 composition as it too lacks an anti-tussive, "consisting of" pyrilamine tannate and phenylephrine tannate. (*See* PR-24 at Cols. 3-4.) Yet, the PTO did not draw this conclusion even though the patent examiner was aware of carbetapentane tannate and its anti-tussive utility, having previously noted that it was a "cough suppressant" while citing the Japanese patent in the First Office Action. (*See* P-35 at 32, 35.)

The examiner still did not allow MedPointe's redrafted claims. She and MedPointe discussed its claims by telephone, including its composition claim. (*See id.* at 90.) MedPointe then submitted additional references - known applications for patents involving mostly tannate-based compositions - at the examiner's request. (*See id.* at 83-85.) These submissions presumably eased the patent examiner's remaining concerns, because she signed, and the PTO issued thereafter, a Notice of Allowability to MedPointe. (*See id.* at 91-95.)

The defendants have not met their "additional burden" of overcoming the deference that is the PTO's due. *See* Am. Hoist, 725 F.2d at 1359. The PTO addressed the obviousness of the '206 patent's application, including whether the prior art

presented a motive or suggestion to re-combine tannate drugs. MedPointe then allayed its concerns.[20] We will give the PTO the deference that it deserves and not revisit the obviousness issue further, with one exception, on these motions.

> (e) The "Candettes" Reference is no More Pertinent than Those Which MedPointe had Disclosed to the PTO

That exception is to "Candettes." (*See* D-15.) It is a combination, available since 1938, of carbetapentane citrate, pyrilamine maleate, phenylephrine hydrochloride and ammonium chloride. (*Id.*) Hi-Tech argues that it too renders the '206 patent obvious. (Hi-Tech Br. at 17-18.) O'Donnell testified that a practitioner of ordinary skill would have discerned a suggestion in the prior art, and would have been technically able, to transform this composition into a slow-release formula simply by replacing the salt form attached to each Candettes pharmaceutical base component with its tannate counterpart. (O'Donnell Testimony, 12-24-03 Tr. at 30-33; *see* PR-27.) He concluded that the obvious result would have been the same composition as that in Claim 1. (O'Donnell Testimony, 12-24-03 Tr. at 30-33.)

This reference was not before the PTO. (*See* P-35 at 74-76:)

> Where prior art that was not before the PTO is produced, the element of deference due the PTO is reduced. However, the production of new prior art does not shift nor lighten nor change the burden of

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[20] Moreover, the comprehensive submission by MedPointe of prior art references further distinguishes this case from *McNeil-PPC* where the Federal Circuit had noted that the patentee had failed to reveal to the PTO an existing reference which taught the "treatment of irritable bowel syndrome with both [the antidiarrheal] and [the anti-gas drug]." *McNeil-PPC*, 337 F.3d at 1369.

> proof that a party attacking the validity of a patent must meet.

Tyco Indus., 914 F. Supp. at 1079; *see also Syntex Pharm. Int'l, Ltd. v. K-Line Pharm., Ltd.*, 721 F. Supp. 653, 658 (D.N.J. 1989). Further, "where the additional prior art cited by the party attacking the validity of the patent is no more pertinent than that considered by the Examiner, the presumption of validity may only be overcome by showing that the Examiner erred in allowing the claims." *Id.* (citing *Am. Hoist*, 725 F.2d at 1359).

The Candettes reference was no more pertinent than those of which the examiner was aware. MedPointe disclosed its existing tannate drugs to the examiner. (P-35 at 74-76.) These included Ryna-12. (*Id.*) MedPointe disclosed other patents and applications involving tannate-based compositions, including the '597 patent. (*Id.* at 82-85.) The patent examiner had previously shown her awareness of non-MedPointe tannate drugs. (*See id.* at 59.)

Candettes, to become Claim 1, would require the ordinarily skilled practitioner to delete the ammonium chloride, transform each remaining active into its tannate salt form, and determine the appropriate dosages of the latter. Both Ryna-12 and the '597 patent's composition merely required adding an anti-tussive, such as carbetapentane tannate, to meet this same end. O'Donnell had, moreover, agreed that he believed the product that "was closest" to Tussi-12D was neither Candettes nor Ryna-12, but Tussi-12, a reference he admitted MedPointe had disclosed to the PTO. (O'Donnell Testimony, 12-24-03 Tr. at 60-62.)

14) We find that, at the requisite level of ordinary skill, it would have been far more likely for a practitioner to have discerned a suggestion or motive in the prior art to add an antitussive to Ryna-12 or the '597 composition than to create a slow-acting, tannate-based composition from Candettes. Both the Ryna-,12 and '597 references were disclosed by MedPointe to the PTO, which thereafter issued the patent regardless.

15) We therefore find the Candettes reference to be "no more pertinent" than the prior art references made to, or cited by, the patent examiner. It does not displace our deference to the PTO or the presumption of validity the `206 patent otherwise receives.

(iii) Differences Between the Prior Art and the Claims

The facts relating to this *Graham* factor are encompassed by the preceding discussion section because the differences between the prior art and Claim 1 are slight. The only difference between Claim 1 and the prior art is that this composition of well-known existing tannate pharmaceuticals had not been made before January 26, 2001. (O'Donnell Testimony, 12-24-03 Tr. At 23, 43, 59.) As the `206 patent itself states, the purported novelty is the re-combination of well-known pharmaceuticals. (P-2, Col. 1.) This is why the putative existence of a suggestion or motive in the prior art to re-combine is the dispositive issue. (*See supra*, § II.B.(2)(a)(ii).)

(iv)Secondary Indicia of Nonobviousness

The fourth Graham factual inquiry relates to secondary considerations, *i.e.*, "objective evidence of nonobviousness." *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 726 (Fed. Cir. 2002). "Objective evidence of nonobviousness, such as commercial success, long felt need for the invention, copying, and failure of others to invent, is relevant, and when present, must be considered." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1555 (Fed. Cir. 1995). "For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995).

Hi-Tech argues that MedPointe has failed to show this nexus. (Hi-Tech Br. at 19-21.) Hi-Tech alleges that MedPointe's citing mere sales data of Tussi-12D is not enough to show the required nexus between this product's supposed commercial success and the merits of the '206 patent. We disagree. MedPointe has shown a prima facie nexus between its evidence of secondary indicia and the merits of the '206 patent. A prima facie nexus "is generally made out when the patentee shows both that there is commercial success, and. that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent." *GPAC*, 57 F.3d at 1580 (quotation omitted).

Tussi-12D has demonstrated commercial success in what is a competitive market, even if its long-term profitability has yet to be established. Edick testified that the public response to Tussi-12D has been "outstanding," citing the feedback MedPointe had received from physicians and patients as well as the drug's sales since its 2002 release. (Edick Testimony, 12-23-03 Tr. at 208-11; *see* P-82.) MedPointe has sold some $11 million of Tussi-12D in suspension and $3 million in tablets. (Edick Testimony, 12-23-03 Tr. at 210.) Although MedPointe had only broken even on Tussi-12D so far, with profits from the suspension making up for an operating loss on the tablets, this underlined the dangers, in Edick's opinion, that his company faced from generics. (*Id.* at 210-16.) Tussi-12D is one of "numerous antitussive/antihistamine/decongestant products available on the market." (PR-9.) MedPointe has many competitors. (Edick Testimony, 12-23-03 Tr. at 242-43.) Moreover, Tussi-12D has been criticized as being "not favorably priced when compared to similar agents." (PR-9.) Despite its price, however, Tussi-12D has been enough of a success that MedPointe has come to depend upon its sale.(Edick Testimony, 12-23-03 Tr. at 210, 238-40.)

15) The Court finds that MedPointe, by demonstrating the commercial success of Tussi-12D, has established a prima facie

nexus between the merits of the composition set forth in Claim 1 and Medpointe's relevant objective evidence. MedPointe's secondary objective evidence thus carries "substantial weight" within our determination of nonobviousness.[21]

This secondary objective evidence is not only limited to the commercial success of Tussi-12D. The amount of copying of Tussi-12D is also a relevant secondary indicator of the. nonobviousness of the '206 patent. In addition to the defendants themselves, two other known generic drug companies, Breckenridge and Morton Grove, tried to copy Tussi-12D within a year of its release. (*See* Edick Testimony, 12-23-03 Tr. at 216-19; Dondeti Testimony, 12-23-03 Tr. at 269-74; P-59; P-72; P-75.)

The failure of others to come up with the composition before MedPointe is also relevant.[22] No one else had formulated and marketed the composition set forth in the '206 patent before MedPointe applied for the patent in January 2001, even though each of the component tannates had long been known to ordinarily skilled practitioners. (O'Donnell Testimony, 12-24-03 Tr. at 23, 43, 59.) Even though each of the active pharmaceuticals has been known since the time of Candettes, no one had formulated a composition of their tannate salts. (*Id.* at 44-45.)

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[21] A lack of objective evidence would not weigh in favor of obviousness. *Miles Labs., Inc. v. Shandon Inc.*, 997 F.2d 870, 878 (Fed. Cir. 1993). We thus still would hold the '206 patent to be nonobvious even if MedPointe was unable to bring objective evidence of secondary indicia of nonobviousness to bear.

[22] It is unclear whether the '206 patent fulfills any "long felt need." As already noted, Tussi-12D is one of many combination cough and cold remedies in general, and one of many tannate-based cough and cold pharmaceuticals in particular. (*See* D-13; D-16; PR-9.)

(v) Conclusion: The Defendants Have Not Been Able to Raise a "Substantial Question" that the `206 Patent is Obvious

The Court, based upon its findings for each *Graham* factor, holds that the defendants have not raised a substantial question -that the `206 patent is invalid for obviousness. MedPointe has shown that this defense, at least for the purpose of these two motions, lacks "substantial merit."

(b) The '206 Patent is not Unenforceable for Inequtable Conduct

Hi-Tech argues that MedPointe's inequitable conduct raises a "substantial question" as to the '206 patent's enforceability. Hi-Tech alleges that MedPointe intentionally omitted the utility of the products and patents it had disclosed to the PTO, and that this was material to patentability. (Hi-Tech Br. at 21-25.) We agree with MedPointe that Hi-Tech's defense lacks merit. (Reply to Hi-Tech Br. at 15-16.)

Inequitable conduct means any "affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." *Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1581 (Fed. Cir. 1996) (quotation omitted). A breach of the duty of candor, when coupled with an intent to deceive or mislead the PTO, constitutes inequitable conduct, which, when proven, renders the patent unenforceable. *Li Second Family Ltd. P'ship v. Toshiba Corp.*, 231 F.3d 1373, 1381 (Fed. Cir. 2000). The party alleging inequitable conduct must prove the threshold elements of materiality and intent by clear and convincing evidence at trial. *Refac*, 81 F.3d at 1581.

The Federal Circuit and PTO observe the same standard of - materiality, *i.e.*, whether a reasonable examiner would consider the omission or misrepresentation important in deciding whether to issue the patent. *Akzo N.V. v. U.S. Int'l Trade*

Comm'n, 808 F.2d 1471, 1481-82 & n.14 (Fed. Cir. 1986) (citing 37 C.F.R. § 1.56(a)). "[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application." 37 C.F.R. § 1.56(b). "Materiality and intent must also be considered together: the more material the omission or misrepresentation, the less intent that must be shown to reach a conclusion of inequitable conduct." *Akzo*, 808 F.2d at 1481-82.

MedPointe has shown that Hi-Tech's inequitable conduct defense lacks "substantial merit." A recitation of the utility of each of the compositions in the products, patents, and applications MedPointe disclosed would have been "cumulative to information already of record." 37 C.F.R. § 1.56(b). The patent examiner had shown in the First Office Action that she understood the utility of Claim 1's three components and chlorpheniramine when she discussed the Weiler study and the Japanese patent. (P-35 at 32-36.) These were the four actives present, in varying doses and combinations, in the eight products MedPointe cited as "material to the patentability" of its application as prior art when it responded to the PTO's Second Office Action. (*Id.* at 74-76.)

The defendants have earlier failed to meet their additional burden of showing that the Court should not defer to the PTO's decision to grant the '206 patent. (*See supra*, § II.B.(2)(a)(ii.c).) We see no reason why we should now assume that the patent examiner and MedPointe's representatives did not recognize the utility of the references MedPointe disclosed during their follow-up telephone conversations. After all, the examiner still had not allowed MedPointe's amended claims, requiring yet another submission detailing known patent applications, before the PTO finally issued the Notice of Allowability. (*See* P-35 at 87.) Given the thoroughness otherwise shown by the PTO and the patent examiner in the Patent File History, Hi-Tech's showing fails to raise a "substantial question" of inequitable conduct.

(3) MedPointe has Shown a Likelihood of Success as to Prasco's Infringement of Claim 1 by C-Tanna 12D

Hi-Tech concedes infringement of the '206 patent, if it is valid and enforceable. (12-22-03 Stip.) Prasco does not concede infringement, arguing that its C-Tanna 12D, as intended by Kiel and revealed by Kiel's tests, has a fourth active ingredient, the decongestant phenylephrine hydrochloride. (Prasco Br. at 7-20.) Prasco argues that the '206 patent's prosecution history requires that Claim 1 have only its three listed components as "active ingredients" and no more; therefore, the presence of a fourth active ingredient in its C-Tanna 12D precludes infringement. (*Id.*)

An infringement inquiry is a two-step process. First, the Court must determine the scope and meaning of the patent claim as a matter of law. *Markman*, 52 F.3d at 979. Second, the properly construed claim is compared to the accused product to determine whether it contains every limitation of the claim or a substantial equivalent of any limitation not literally present. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991). The comparison of claims to the accused product, and the corresponding determination of infringement, is a question of fact. *Tanabe Seiyaku Co. v. U.S. Int'l Trade Comm'n*, 109 F.3d 726, 731 (Fed. Cir. 1997).

The Court has already construed Claim 1 of the `206 patent. (*See* supra, § II.B.(1).) We now compare Claim 1, as construed, to the accused product, C-Tanna 12D, in order to "determine whether all of the claim limitations are present either literally or by a substantial equivalent." *Young Dental Mfg. Co. v. Q3 Special Prods.,Inc.*, 112 F.3d 1137, 1141 (Fed. Cir. 1997). MedPointe, as a patentee moving for preliminary injunctive relief, must show that it is likely to prevail as to its burden of showing literal infringement or infringement under the doctrine of equivalents. *H.H. Robertson*, 820 F.2d at 390; *Boehringer*, 984 F. Supp. at 262.

(a) C-Tanna 12D's Likely Infringement of the '206 Patent as of December 17, 2003 Shown by Prasco's Various Assertions

Prasco asserted that its C-Tanna 12D was the functional equivalent of Tussi-12D, MedPointe's commercial embodiment of the '206 patent, until this litigation was well under way. Prasco produced package inserts for C-Tanna 12D tracking the pertinent information on the Tussi-12D package insert. (*See* P-6; P-48.)

We compare the assertions on the C-Tanna 12D package insert to our construction of Claim 1, making the following findings:

1) C-Tanna 12D tablets and suspension are "indicated for the symptomatic relief of cough associated with respiratory tract conditions such as the common cold, bronchial asthma, acute and chronic bronchitis." (P-6.) This language tracks both the first of our constructions, *see supra* § II.B.(l)(b)(i), and much of the pertinent language in Claim 1 itself. (*See* P-2, Col. 4.)

2) C-Tanna 12D "is an antitussive/antihistamine/nasal decongestant combination available for oral administration as Tablets and as a Suspension" that contains three ingredients: carbetapentane tannate, pyriliamine tannate, and phenylephrine tannate. (P-6.) These are the same three tannates recited in Claim 1 of the `206 patent. (P-2, Col. 4.)

3) Because C-Tanna 12D's listed ingredients must be present in "pharmaceutically effective amounts" in order to provide, as its label and package insert claim, the "symptomatic relief of cough," C-Tanna 12D's package insert implicates our second construction. (*See supra*, § II.B.(1)(b)(ii).)

4) Nothing on the label or package insert announces the presence of a fourth "active ingredient" within the composition for C-Tanna 12D that might render it non-infringing. (*See* P-6.)

5) If such an extra "active ingredient" was present in less than "pharmaceutically effective amounts," it would not render C-Tanna 12D non-infringing, given our third construction. (*See supra*, § II.B. (l) (b) (ii) .)

6) The dosage period of such an extra "active ingredient" in C-Tanna 12D must be taken into account in determining whether it is capable of being present in "pharmaceutically effective amounts," given our fourth construction. (*See supra*, § II.B.(1) (b) (iii) .)

Prasco represented C-Tanna 12D to the electronic databases used for the ordering of prescription drugs, such as the First Data Bank, as a suitable generic substitute for Tussi-12D. (P-73; P-222; *see* P-93; P-94; P-95.) Prasco's Rule 30(b)(6) witness, Vraniak, admitted that the proposed labels made no mention of the presence of phenylephrine hydrochloride as one of the active ingredients in C-Tanna 12D. (Vraniak Tr. at 21-45, 114-22.) As of the date of his deposition, December 17, 2003, Vraniak did not think that there was any intent on Prasco's part to change the package insert for C-Tanna 12D. (*See id.* at 30-31.)

We thus further find that:

7) As of the time temporary restraints were entered against it and continuing through December 17, 2003 at the earliest, Prasco intended to market and ship C-Tanna 12D as a generic version of Tussi-12D.

Prasco argues that MedPointe has not cited any evidence of Prasco's infringement beyond C-Tanna 12D's labels and package inserts. (Prasco Br. at 14.) MedPointe, however, has shown that Prasco was: marketing C-Tanna 12D as a generic version of Tussi-12D; took orders for its product; and, was ready to ship when temporary restraints were put into place. (Vraniak Tr. at 82-122.)

(b) Our Construction of Claim 1 Does not Preclude C-Tanna 12D's Infrinqement even if

it is Partially Composed, as Kiel's Tests Claim, of Phenylephrine Hydrochloride

Prasco changed its characterization of the composition of C-Tanna 12D during this litigation. Prasco believed in the truth of the product information Kiel provided for the package inserts Prasco printed for C-Tanna 12D until informed otherwise by Kiel several weeks before the injunction hearing. (Vraniak Testimony, 12-23-03 Tr. at 261-63.) Kiel's Thomas testified that the TCT procedure Kiel uses to produce C-Tanna 12D intentionally has phenylephrine hydrochloride as both a starting raw material and an "active ingredient" end product. (Thomas Testimony, 12-23-03 Tr. at 174-75, 192-95; *see* P-400; PR-23.)

This argument is of no moment because an "active ingredient" is only present in "pharmaceutically effective amounts" in the Claim 1 "therapeutic composition" if the relative dosage period of the "active ingredient" is comparable to that of the tannatebased "therapeutic composition" itself. (*See supra*, § II.B.(1) (b) (iii).) The composition in Claim 1 consists of "stable" tannates in "pharmaceutically effective amounts." (P-2, Col. 4.) C-Tanna 12D is a composition that includes the same three tannates as Claim 1 and claims efficacy for the "symptomatic relief of cough." (*Compare id. with* P-6.) Wainer testified that the dosage period for the C-Tanna 12D composition would be twelve hours. (Wainer Testimony, 12-22-03 Tr. at 102.) In contrast, phenylephrine hydrochloride has a dosage period of four hours. (*Id.* at 101-02.) Long before the tannate active ingredients in C-Tanna 12D would have run their course, a warm-blooded animal would have metabolized all the phenylephrine hydrochloride from its system. (*Id.* at 102-03.) The phenylephrine hydrochloride would thus no longer be "pharmaceutically effective." (*See, e.g., id.* at 97-103.)

We therefore further find that:

8) Phenylephrine hydrochloride cannot be an "active ingredient" present in "pharmaceutically effective amounts" in

C-Tanna 12D. Even if it is pharmacologically-active, the brief dosage period of phenylephrine hydrochloride compared with that of the listed tannate composition renders it impossible for it to be "pharmaceutically effective" as that term has been interpreted by the Court. (*See supra*, § II.B. (1) (b) (iii) .)[23]

10) The presence of phenylephrine hydrochloride in C-Tanna 12D does not render the accused product non-infringing because our construction of Claim 1 permits "active ingredients" in less than "pharmaceutically effective amounts." (*See supra*, § II.B. (1) (b) (ii) .) [24]

(c) Conclusion: MedPointe has Demonstrated That it is Likely to Succeed as to Prasco's Infringement of the '206 Patent

The Court holds that, based upon the above findings, MedPointe has met its burden of showing that it is likely to demonstrate that Prasco's C-Tanna 12D literally infringes the '206 patent.

(4) Conclusion: MedPointe Likely to Succeed on the Merits

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[23] We make no finding as to where the phenylephrine hydrochloride in C-Tanna 12D came from. Whether it is an impurity, an unreacted raw material, a process contaminant or an intended but unrevealed "active ingredient" makes no difference, given our construction of Claim 1.

[24] MedPointe's settlement with Kiel as to their prior litigation concerning the '597 patent is irrelevant to this motion. (*See* PR-24; PR-25; PR-26.) MedPointe's recitation therein that Kiel had not infringed the '597 patent has no bearing on this motion, if for no other reason than the language of the two composition patents is critically different. Claim 1 of the '597 patent uses the transitional phrase "consisting of," a "closed" term, compared to the '206 patent's use of the "open" transitional phrase "comprising." (*Compare* PR-24 with P-2.)

The Court holds that MedPointe has met its burden of showing likelihood of success on the merits in general and in regards to -both defendants' above-noted defenses.

C. Irreparable Harm

A rebuttable presumption of irreparable harm arises when the patentee has made a "clear showing" of both infringement and the validity of the patent in question. *Amazon.com*, 239 F.3d at 1350 (citations omitted). "This presumption derives in part from the finite term of the patent grant, for patent expiration is not suspended during litigation, and the passage of time can work irremediable harm." *H.H. Robertson*, 820 F.2d at 390.

(1) MedPointe Entitled to Presumption of Irreparable Harm

Prasco and Hi-Tech contest MedPointe's entitlement to the presumption of irreparable harm. (Prasco Br. at 32-33; Hi-Tech Br. at 25-27.) We agree with MedPointe and hold that MedPointe has made a "strong showing" as to the '206 patent's validity and the defendants' infringement thereof. MedPointe's strong showing as to its likelihood of success on the merits entitles it to the presumption of irreparable harm. We also note, however, that MedPointe has made an independent showing as to its danger of irreparable harm in the absence of injunctive relief. (*See infra*, § II.C. (3) .)

(2) The Defendants Have not Rebutted the Presumption of Irreparable Harm

The defendants do not directly argue that they can rebut the presumption if it applies. (*See* Prasco Br. at 33-36; Hi-Tech Br. at 25-28.) Nor do the defendants' arguments that MedPointe will not suffer irreparable harm were we to deny it injunctive relief implicitly rebut the presumption of irreparable harm. Evidence that will rebut the presumption is:

> evidence that (1) the non-movant has or will soon cease the allegedly infringing activities, thus making an injunction unnecessary; (2) movants have engaged in a pattern of granting licenses under the patent, such that it may be reasonable to expect that invasion of the patent right can be recompensed with a royalty rather than with an injunction; or (3) movants unduly delayed in bringing suit, thereby negating the idea of irreparability.

Polymer Techs., 103 F.3d at 973.

> (a) Kiel's Unreliable Testing Fails to Raise a Substantial Question as to Whether Tussi-12D Itself is Protected by Claim 1 or of C-Tanna 12D's Likely Infringement of it

Prasco initially argues that MedPointe cannot be irreparably harmed because the supposed embodiment of the '206 patent, Tussi-12D, does not fall under its protection. (Prasco Br. at 34-36.) It alleges that Kiel's testing of Tussi-12D demonstrates that Tussi-12D has an unrevealed fourth "active ingredient" which removes it from the scope of the '206 patent. (*Id.*) MedPointe replies that Prasco's test data is inadmissible. (Reply to Prasco Br. at 25.) The Court notes that it has not made a final holding as to the admissibility of Thomas' testimony or his test data, the latter having been provisionally admitted for the purposes of the hearing. (12-23-03 Tr. at 151-52; *see* PR-23.)

The Court finds, for the purpose of Prasco's opposition to the present motion, that Thomas's methodology and test data are not reliable. Thomas designed a chemical assay that he asserts shows the presence of a non-tannate phenylephrine in both C-Tanna 12D and Tussi-12D. (PR-23; *see* Thomas Decl. ¶¶ 3-7; Thomas Testimony, 12-23-03 Tr. at 131-58.) His methodology, however, relies on the assumption that phenylephrine tannate is

non-soluble. (Wainer Decl. ¶ 47; *see* Thomas Testimony, 12-23-03 Tr. at 138, 196-98.) Wainer asserts that Thomas's test takes no account of the "expected solubility of phenylephrine tannate in water under his test conditions." (Wainer Decl. ¶ 47.) Thomas would have had to factor out the solubility of phenylephrine tannate, because his test only measures the total amount of soluble phenylephrine, regardless of source. (Wainer Testimony, 12-24-03 Tr. at 107-16.) Wainer's rebuttal testimony is especially credible as he has presented a hypothetical validation assay which could measure the phenylephrine within a sample in its hydrochloride and tannate forms by measuring all relevant indicators: phenylephrine, tannic acid, and chloride ions. (Wainer Decl. ¶¶ 51-59; *see* Wainer Testimony, 12-24-03 Tr. at 110-16.)

Thomas testified that measuring phenylephrine alone sufficed because one could safely assume that phenylephrine tannate was insoluble and thus the soluble phenylephrine that his assay separately measured thus have come from phenylephrine hydrochloride. (Thomas Testimony, 12-23-03 Tr. at 137-39.) Thomas's testimony, however, lacks credibility. Not only is Wainer's critique well-taken, but the Court also notes that a Kiel patent application, P-97, on which Thomas is listed as an inventor, acknowledges the solubility of phenylephrine tannate, stating that: "in the case of phenylephrine, the tannate salt showed partial solubility in purified water." (P-97, Spec. ¶ 58.)

We will thus disregard, for the purposes of this motion, Thomas's opinion that there is an undisclosed non-tannate form of phenylephrine in Tussi-12D or that Prasco's C-Tanna 12D has phenylephrine hydrochloride. We note, however, that Tussi-12D would still be protected by our construction of Claim 1 even if Thomas's testing reliably demonstrated that Tussi-12D has an additional "active ingredient" in less than "pharmaceutically effective amounts," keeping relative dosage periods in mind. By that same token, our finding of

infringement by C-Tanna 12D of Claim 1 would be similarly unaffected by our finding Thomas's tests, and their data, reliable. (*See supra*, § II.B.(3)(c).)

(b) MedPointe has Zealously Guarded its Rights Under the `206 Patent, has Never Granted a License Under it, and Credibly Asserts that it has No Intention of Granting Any Licenses

The defendants do not attempt to make a showing as to the last two factors that may otherwise rebut the presumption of irreparable harm. MedPointe has not granted any license under the '206 patent and credibly avows that it has no intent to ever do so. (Edick Testimony, 12-23-03 Tr. at 220-21.) MedPointe has zealously guarded its rights under the '206 patent through litigation. (*Id.* at 216-19, 241; *see* P-59; P-75.)

MedPointe, moreover, did not delay in seeking this relief. MedPointe filed Verified Complaints against both defendants and moved for injunctive relief at the moment each was preparing to ship generic versions of Tussi-12D. (*See* Prasco Compl. ¶¶ 17-19; Hi-Tech Compl. ¶¶ 17-19; Vraniak Tr. at 83; Seltzer Tr. at 89.) There has been no undue delay.

(c) The Court Does Not Now Find Relevant Prasco's Assertion that it Would Change its Labels and Package Inserts if Necessary to Forestall our Awarding MedPointe Injunctive Relief

Hi-Tech does not present evidence as to the first factor that could rebut the presumption of irreparable harm, stipulating that its Tannate-12DS infringes the '206 patent. (12-22-03 Stip.) Prasco, however, stated at the hearing that it would be inappropriate for the Court to award injunctive relief to MedPointe because Prasco's labels, package inserts and submissions to the electronic databases were all "subject to

correction." (12-22-03 Tr. at 34-37.) Prasco's CFO testified that its goal was to "do exactly what's right from a regulatory perspective in listing components on the label." (Vraniak Testimony, 12-23-03 Tr. at 264.)

We regard Prasco's stated intent to consider re-labeling C-Tanna 12D to show that it contains phenylephrine hydrochloride, showing its allegedly non-infringing composition, as equivocal at best. Prasco's CFO testified that his Rule 30(b)(6) deposition for Prasco took place before he and others at Prasco had a chance to discuss the company's options, a process he asserted had begun by the time of the hearing. (Vraniak Testimony, 12-23-03 Tr. at 263-65.) Vraniak stated that Prasco would re-label and de-link C-Tanna 12D as a Tussi-12D generic in the applicable databases if it determined that doing so "was appropriate." (*Id.* at 267.) Prasco had as of then not, however, come to any such decisions and was still engaged in internal discussions. (*Id.* at 265-66.)

The Court finds that Prasco's assertion that it is willing to change its characterization of C-Tanna 12D is insufficient to rebut the presumption of irreparable harm or to forestall our awarding injunctive relief to MedPointe. Prasco has not shown that it will unequivocally cease its threatened infringement of the '206 patent "soon." We note that our award of injunctive relief to MedPointe, however, is without prejudice to Prasco's arguing non-infringement at trial or later moving to modify or vacate our preliminary injunction.

(3) MedPointe Likely to Succeed as to Irreparable Harm

Hi-Tech argues that MedPointe cannot show the requisite danger of irreparable harm because it can be compensated through damages. (Hi-Tech Br. at 27-28.) MedPointe replies that if the market for Tussi-12D is "genericized," its continued existence as a viable company will be jeopardized. (Reply to

Prasco Br. at 21-25; Reply to Hi-Tech Br. at 16-21.) We agree with MedPointe.

MedPointe's status as a patentee that has shown the likely validity of its patent weighs in its favor: "Because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole." *Reebok*, 32 F.3d at 1557; *see A.K. Stamping*, 106 F. Supp. 2d at 655. However, "neither the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying [injunctive-relief]." *Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991). Yet, "'economic' considerations such as lost market share, monies expended on product development, and reduced profits are specifically among the factors courts consider in finding that a patent holder will face irreparable harm." *A.K. Stamping*, 106 F. Supp. 2d at 655.

MedPointe has demonstrated that Tussi-12D's market share will likely plummet if generic versions are allowed. Tussi-12D is comparable enough to its predecessors that we find MedPointe's analogy to the generic-induced erosion of its market share in three such drugs, Ryna-12, Tussi-12 (Reformulated) and Rynatan, as probative. (Edick Testimony, 12-23-03 Tr. at 221-26; *see* P-86; P-223; P-224; P-225.)

MedPointe now has the entirety of the market represented by Tussi-12D. Edick admitted that the data required to calculate MedPointe's losses to Prasco was available, given the assumption that every Prasco sale indicates one lost to MedPointe. (Edick Testimony, 12-23-03 Tr. at 235-38.) We do not think, however, that this renders MedPointe's potential losses as fully compensable in monetary damages. The presence of other potential infringers is a further factor that courts have relied on in finding irreparable harm. *Hybritech*, 849 F.2d at 1456. Prasco does not exist in a vacuum. Tussi-12D faces generic competition not only from it and Hi-Tech, but

from Morton Grove and Breckenridge as well. (P-59; P-72.) Sales by any of them -- and by others who might yet enter the market -- would represent losses to MedPointe. Leaving aside the difficulties that this may bring MedPointe for calculating its losses, the existence of these other infringers, especially given their demonstrated interest in marketing generic versions of Tussi-12D, weighs in favor of our finding the likelihood of irreparable harm.

MedPointe's assertion that it faces financial ruin if the market for Tussi-12D is "genercized" is especially credible in light of the nature of this competition. "The opportunity to practice an invention during the notoriously lengthy course of patent litigation may itself tempt infringers." *H.H. Robertson*, 820 F.2d at 390. Were genericization to take place, MedPointe's continued viability would be questionable. (Edick Testimony, 12-23-03 Tr. at 226-28, 238-39.) At the very least, MedPointe's goodwill would suffer, as would its ability to support and market Tussi-12D by educating physicians in its use. (Edick Pr. Decl. ¶¶ 15-18.) So would its research and development budget. (Edick Testimony, 12-23-03 Tr. at 254.)

The Court thus finds that MedPointe has met its burden of showing that it is in danger of irreparable harm if it does not receive injunctive relief.

D. Balance of Hardships

"The magnitude of the threatened injury to the patent owner is weighed, in the light of the strength of the showing of likelihood of success on the merits, against the injury to the accused infringer if the preliminary decision is in error." *H.H. Robertson*, 820 F.2d at 390; *see Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990). We are not, however, required to make an explicit finding as to this factor, nor is MedPointe necessarily to be denied a preliminary injunction if the evidence is otherwise at equipoise. *Hybritech*, 849 F.2d at 1457-58.

We have already found that MedPointe has made a "strong showing" as to the validity and infringement of the '206 patent. *See supra*, § II.C.(1). This entails a strong showing as to its general likelihood of success. It is appropriate to consider the size and relative position of the parties and the effect that awarding a preliminary injunction will have on each. *Ill. Tool Works*, 906 F.2d at 683-84. All three parties are relatively small. All three stand to lose profits. MedPointe, however, has shown that it stands to lose more than sales and profits; it has spent some $3 million developing Tussi-12D. (Edick Testimony, 12-23-03 Tr. at 206, 249.) Its continued viability is at stake. (*Id.* at 226-28.) In contrast, Prasco and Hi-Tech have respectively expended $10,000 and $100,000 in start-up costs. (Vraniak Tr. at 45-47; Seltzer Tr. at 26-38.)

The Court therefore finds that the balance of hardships weighs in MedPointe's favor.

E. The Public Interest

The Court finds that the public interest is not against our grant of a preliminary injunction. Both the public interest and the possibility of harm to others are factors to be considered in the preliminary injunction inquiry. *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1579 (Fed. Cir. 1983). An overriding public interest may prevent the issuance of an injunction. *Hybritech*, 849 F.2d at 1458. Generally, however, "no public interest is served by allowing patent infringement." *A.K. Stamping*, 106 F. Supp. 2d at 656 (citations omitted).

Considerations such as the possibility of a lower price are not grounds for infringing a patent. *Payless Shoesource, Inc. v.Reebok Int'l Ltd.*, 998 F.2d 985, 991 (Fed. Cir. 1993). This undermines the defendants' otherwise reasonable argument that the public interest favors the availability of cheap generic drugs. (*See* Prasco Br. at 37; Hi-Tech Br. at 30-31.) We share the reasoning of the *A.K. Stamping* court that whatever "interest exists in having more suppliers put their products on the market

is strongly outweighed by the public policy in favor of enforcing patent rights and encouraging inventors to develop new products, and by the showing [MedPointe] has made on the other prongs." A.K. Stamping, 106 F. Supp. 2d at 656.

We thus find that the public interest does not outweigh MedPointe's showing on the other three prongs.

III. CONCLUSION

This Court has found that Medpointe has satisfied all four factors required to demonstrate its entitlement to a preliminary injunction pursuant to Federal Rule of Civil Procedure 65. The Court will consult with counsel to determine the form of the order and the bond requirements.

s/

MARY L. COOPER

United States District Judge